



Standardization

National Strategy for CBRND Standards

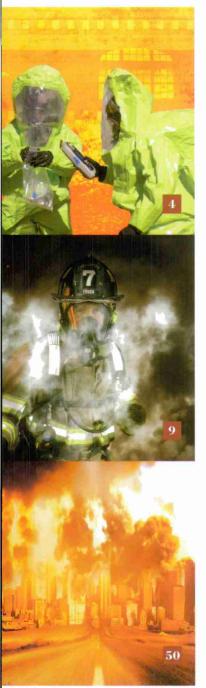
Status of the GRaDER Program

Trace Explosives

All Disaster Recovery Planning Is Local

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Contents April/September 2012

- 1 Director's Forum
- 4 A National Strategy for CBRNE Standards
 Why It's So Important
- 9 Voluntary Consensus Standards for Chemical Detectors
- 16 Development of Voluntary Consensus Standards That Define the Performance of Biological Threat Detectors
- 24 Building a National Biothreat Response Capability
- 32 Status of the GRaDER Program
- 37 Trace Explosives
 Reference Materials and Process Optimization through Training
- 43 What Every First Response Organization Should Know About Its CBRN Respirators
- 50 All Disaster Recovery Planning Is Local
 How Grassroots Efforts Can Inform Federal Disaster Recovery Practices

Departments

56 Program News 59 Events 60 People

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Director's Forum



In this issue of the *Defense Standardization Program Journal*, we are focusing on standardization efforts underway at the Department of Homeland Security (DHS). Because of this issue's size, we have decided to let it span a 6-month period. It is my pleasure to turn over my column in this issue to Mr. Philip Mattson, Acting DHS Standards Executive.

> Gregory E. Saunders Director, Defense Standardization Program Office

MESSAGE FROM THE ACTING DHS STANDARDS EXECUTIVE

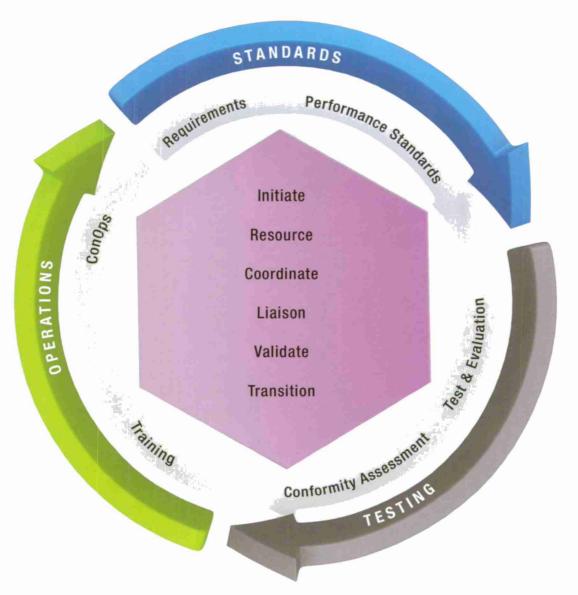
This is the second special Journal issue dedicated to the DHS standards program. The July/December 2007 issue covered a broad spectrum of DHS's standards activities, such as the development of standards for x-ray security screening, robotics, and biometrics. This issue highlights key aspects of DHS's implementation of the national strategy for chemical, biological, radiological, nuclear, and explosives (CBRNE) standards.

DHS's implementation of the CBRNE standards strategy is coordinated through the DHS Standards Council, and standards development activities are executed by the Science and Technology (S&T) Directorate, as well as by the various DHS components. The goal is to develop and implement standards as the basis for providing users an effective capability, a capability derived from requirementsbased performance standards, validated by appropriate test methods, confirmed by an appropriate conformity assessment method, and supported by training and facilitation of the users' concept of operations (ConOps) for employing that capability. In short, our goal and function is to facilitate the

transition from documented standards, validated by appropriate testing, to fielding of an operationally effective capability.

When developing new standards, the DHS S&T Directorate and the other DHS components work closely with users, technology developers, scientists and program managers, and standards developing organizations. The DHS standards development model incorporates user requirements and performance standards, test and evaluation (T&E) protocols, and conformity assessment. The standards development cycle engages users, developers, threat analysts, and standards experts to develop and transform user requirements—which consider the environment, threats, and technology capability—into performance standards that reflect measurable specifications. The performance standards are the basis for the development of T&E protocols, as well as templates for laboratory testing. The protocols and templates are incorporated into T&E and conformity assessment programs, which measure and document the performance of technology against the standard.

FIGURE 1. DHS Standards Development Model



To fully implement this standards-based capability, users must be trained on the capabilities and limitations of equipment that conforms to the standard. That, in turn, must be integrated into the standard operating procedures (SOPs) and ConOps employed by the users. Although standards and testing are critical elements, the effective integration of this capability into operations is the ultimate goal.

The DHS standards development model enables continuous improvement to address dynamic threats, changing technologies, evolving operations, and lessons learned. The model is a flexible process for developing standards that encompass the hierarchy of

homeland security mission elements, from performance standards that support equipment purchases to comprehensive system-level standards that provide guidance and best practices to support the Department's national-level initiatives.

DHS's S&T Directorate facilitates the standards development process through the following activities:

Initiate. We facilitate the formation of a team to develop the standard. The team consists of key stakeholders, including an identified DHS customer, to appropriately scope and schedule the standards project for effective transition.

- Resource. We coordinate and establish the resource plan for the effort, which includes funding and personnel decisions.
- Coordinate. We ensure activities and information flows throughout the standards development process, from one phase to the next as different groups are established to do the various tasks.
- Liaison. We ensure the transition of activities with the appropriate performers throughout the standards development process with buy-in from the key stakeholders/customers and with related external activities.
- Validate. We ensure that the standards products performance specifications and test methods are complete and tested to the extent possible. It is critical to validate these steps to ensure that the standard and test methods meet our requirements.
- Transition. We assist with moving the standard into training, ConOps, and procurement (or a grants program) and ensure that the standard is being used by the DHS customer.

The success of a standards infrastructure is clear when a straight line can be drawn from the standard to confidence in results. For example, standards for personal protective equipment address design, application, performance, handling, and testing. The use of those standards to produce the equipment—combined with appropriate guidance, training, SOPs, and ConOps—will give users of the equipment confidence that they will be protected. And the nation can be confident that our first responders will go home safely from an incident.

DHS's standards development model can be mapped almost directly to the national strategy for CBRNE standards. The DHS implementation of the strategy is focused on the DHS mission and limited by our resources and capabilities. The first article in this issue addresses the importance of having a national strategy for CBRNE standards and shows the alignment between the goals articulated in ANational Strategy for CBRNE Standards and the status of DHS's implementation of the strategy. The other articles in this Journal address some of our individual projects related to CBRNE standards. Those projects clearly support and further the implementation of the goals of the national strategy.

Philip J. Mattson

Acting DHS Standards Executive and Acting Director

Office of Standards Acquisition Support and Operations Analysis Group Science and Technology Directorate Department of Homeland Security

A National Strategy for CBRNE Standards Why It's So Important

By Tod Companion



Our nation has long been faced with hazards, both man-made and natural, and our ability to respond effectively to those hazards has often been hampered by the lack of standardization. For example, in 1871, 1889, and 1904, enormous fires ravaged Chicago, Seattle, and Baltimore, respectively. The equipment, infrastructure, and preparedness of those cities influenced the response to those fires:

- In Chicago, vulnerable construction (elevated wood sidewalks and wood-paved streets) and poor communication led to a rapid conflagration and a misdirected response. As a result, Chicago developed a fire code for its buildings and established an outstanding firefighting force.
- In Seattle, the lack of a public water supply, haphazard street construction, and an allvolunteer firefighting force left the main commercial sector of this young city devastated. Within months, Seattle responded with public infrastructure improvements: a public water system without wooden pipes, a new plan for wide streets, and a professional firefighting force.
- In Baltimore, heavy winds fanned a blaze and, when the fire quickly spread, Baltimore requested help via telegraph. Firefighters came from as far away as Philadelphia, PA, and Richmond, VA, but their hose couplings and equipment weren't compatible. Because of that incompatibility, some 140 acres of Baltimore burned.

The National Board of Fire Underwriters had been stressing the need to standardize since 1872, but at the time of the Baltimore fire in 1904, more than 600 different sizes and variations of fire hose couplings were in use in the United States. Manufacturers used the variations to their competitive advantage, making it difficult for fire companies to switch vendors. But the risks to people and property were magnified.

In 1905, a committee of the National Fire Protection Association established a national standard for the diameter and threads per inch for fire hydrants and hose couplings. The standard specifies that fire hydrants have 2.5-inch hose connections with 7.5 threads per inch and that pumpers have 4.5-inch connections with 4 threads per inch. The standard was—and still is—known as the Baltimore standard and remains the national standard for fire hose couplings to this day.

Today, there are standards for many types of first-responder equipment—not just hose connections. Personal protective equipment, radios, and many other types of equipment are standardized. However, today's equipment contends with a complex range of threats: chemical, biological, radiological/nuclear, and explosives (CBRNE). Concerns about CBRNE hazards have led to a time of reflection for the homeland security community. What has the decade since 9/11 taught us? How have our responses to threats changed? What have we improved? What can we do next?

From the response community, we have heard repeatedly that there is no "chem response" or "bio response": there is a response. Any technology we develop will be useful only to the degree it provides utility or capability to this response. This is a crucial difference; widening our perspective will serve the response community better, and the nation more effectively, as we look to "all hazards."

In dialogue with the response community, it is clear that deciding what to buy is still a challenge. Whether it is tight state and local budgets, strict deadlines for expenditures, or lack of knowledge, it appears that knowing what to buy—indeed, *whether* to buy—is a key question.

CBRNE response technologies do not exist in a vacuum. They are tools in the hands of users. Because of the diversity of users (a police officer, firefighter, hazardous materials [HazMat] technician, security officer, National Guardsman, etc.) and the scope of hazards, we must look beyond the performance standards for a device. Instead, we must look at the integration of the technology into the overall operations of the users in the environment where they work. A concept of operations (ConOps) is not a new idea, but it is something that has often come late in the standards development process. Considering the ConOps as we develop technical performance standards moves us from looking just at the device and its function to seeing a broader response picture. We now regard the device and the user as components of a response capability.

To that end, the White House Committee on Homeland and National Security, part of the National Science and Technology Council, chartered the Subcommittee on CBRNE Standards to look at the complete picture of CBRNE response and the standards needed to support that response. Working across the federal domain, and with the first-responder community, the subcommittee quickly identified key elements for effective standardization and capability delivery. Using the best models from different parts of the government and from different communities, the subcommittee developed a strategy that has high-level goals, but is grounded in successful efforts. The subcommittee articulated those goals in *A National Strategy for CBRNE Standards*, published in May 2011.

The subcommittee will create a plan for achieving the strategy. At the same time, the Department of Homeland Security (DHS) has begun implementing aspects of the strategy through its standards development model. Table 1 shows the alignment between the goals articulated in *A National Strategy for CBRNE Standards* and the status of DHS implementation of the strategy.

In this issue of the *Defense Standardization Program Journal*, elements of the national strategy for CBRNE standards are woven throughout programs at DHS, DoD, the Environ-

TABLE 1. Alignment of CBRNE Standards Goals and the DHS Standards Development Model

Goals from <i>A National Strategy for CBRNE Standards</i>	DHS implementation of the strategy through the standards development model
Establish an interagency group for CBRNE standards to promote the coordination of these standards among federal, state, local, and tribal communities.	In DHS, this group consists of the DHS Standards Executive, working in coordination with the DHS Standards Council and supported by the DHS Science and Technology Directorate. The standards developed and adopted by DHS are, in turn, implemented by the federal, state, local, and tribal communities through DHS grants, guidance, training, and other activities and functions.
Coordinate and facilitate the development of CBRNE equipment performance standards and promote the use of standards for federal, state, local, and tribal communities.	The development of the performance standards, with the ultimate objective of delivering standards-based capabilities to the users, forms the heart of the DHS standards development model.
Coordinate and facilitate the development and adoption of interoperability standards for CBRNE equipment.	Although the development and adoption of interoperability standards are not explicitly called out in the DHS model, it is a constant consideration throughout the process. DHS has, in some cases, supported the development of specific interoperability standards. Interoperability is also addressed in a different context, ensuring that our standards are interoperable and support the users' concept of operations, and that the new capabilities are integrated into the overall operations, and not just limited to the specific technology addressed in a given standard.
Promote enduring CBRNE standard operating procedures for federal, state, local, and tribal use to improve national preparedness and response.	DHS has developed and will continue to support the development of guidance, protocols, processes, and training that, in turn, will help state, local, tribal, and private-sector entities tailor their own operating procedures.
Establish voluntary CBRNE training and certification standards for federal, state, local, and tribal communities and promote policies that foster their adoption.	DHS has developed and will continue to support the development of guidance, protocols, processes, and training that, in turn, will help state, local, tribal, and private-sector entities tailor their own procedures.
Establish comprehensive CBRNE equipment testing and evaluation (T&E) infrastructure and capability to support conformity assessment standards.	DHS does not have an extensive CBRNE T&E infrastructure, but the standards and test methods DHS develops in coordination with the private sector and other federal activities that own and operate T&E infrastructure allow us to leverage the existing capabilities. In addition, DHS is seeking to develop standards that can be used by multiple agencies, serving as a foundation for building agency-unique requirements.

mental Protection Agency, the National Institute of Standards and Technology (NIST), and the National Institute for Occupational Safety and Health (NIOSH) within the Department of Health and Human Services. The articles are organized to follow the CBRNE abbreviation, but instead of a summary of the efforts in each area, we've challenged the authors to discuss the application of their efforts in the response community through the goals articulated in the national strategy:

- Pamela Chu and Charles Laljer describe work in chemical threat detection and the establishment of standards and test methods that support both users and industry.
- Matt Davenport then addresses biological threats with a discussion on the development of standards in biodetection.
- Jayne Morrow, Clay McGuyer, Bryon Marsh, and David Ladd build on the biothreat discussion by addressing how various performance standards fit into the response framework, moving from performance standards and sampling to training and certification. This includes the crucial perspective of the National Guard Bureau and the HazMat community.
- Leticia Pibida, Cheri Hautala-Bateman, Huaiyu Heather Chen-Mayer, Julian Hill, and Michael Unterweger provide a brief overview of the most mature area in CBRNE standards: radiological detection and the work in the DHS Graduated Rad/Nuc Detector Evaluation and Reporting program supported by the DHS Domestic Nuclear Detection Office.
- Jennifer Verkouteren presents a very successful collaboration between DHS and NIST in support of trace explosives detection and the approach used to built on the spectrum of activities described in the national strategy, from performance standards to training.
- Richard Metzler and Jonathan Szalajda focus more on the "whole of government" mission—the full response from emergency to recovery—with a discussion of work by NIOSH on personal protective equipment for CBRN response.
- Ann Lesperance, Jessica Sandusky, and Steve Stein close the issue with a discussion of a bottom-up approach to recovery planning, the elements of a local recovery framework, and the advantages and challenges of this approach.

These articles should pique interest in, and ideally support of, efforts to ensure the development of effective and interoperable CBRNE technology, as well as its appropriate deployment (including user training)—in short, to provide a true all-hazards response capability. Only when responders have equipment that works, training to support its use, and true interoperability will the nation be prepared for a CBRNE hazard.

About the Author

Tod Companion, PhD, is the program manager for Standards Identification and Development in the Office of Standards within the DHS Science and Technology Directorate. He serves as the executive secretary for the Subcommittee on CBRNE Standards of the Committee on Homeland and National Security and led the development of the National Strategy for Homeland Security. Dr. Companion is a DHS Senior Fellow and works across DHS and the federal government to coordinate standards for detection, response, and recovery from all hazards. His career has found him at NASA, the U.S. Senate, and many parts of DHS.

Consensus Standards 1 Detectors Pamela Chu and Charles Laljer

In the event of a toxic chemical release, either through an act of terrorism, industrial accident, or natural disaster, effective incident management requires accurate real-time chemical analysis of the materials in question. To help ensure that proper evacuation and decontamination procedures can be initiated, it is critical for first responders and soldiers to have chemical detection equipment for identifying the chemical hazard, the threat level, and the boundaries of the contaminated area. Furthermore, the detection equipment must operate reliably and accurately, and the users must have confidence in the equipment. Correctly identifying and quantifying hazardous chemical vapors in the field are challenging tasks; hundreds of industrial chemicals are toxic at low concentrations (from part-per-million to subpart-per-billion concentrations). Environmental conditions and commonly occurring benign chemicals can affect the measurement of vapors of interest either by masking the presence of a toxic material or by triggering an alarm when toxic materials are not present. False negative alarms expose people to significant health risks, while false positive alarms cause loss in confidence in the equipment and unnecessary and costly evacuations.

With 207 chemical detectors listed in the Guide for the Selection of Chemical Detection Equipment for Emergency First Responders, detection equipment purchasers have many options. For example, up to 10 different types of chemical measurement technologies are used in point detectors for chemical warfare agents (CWAs), toxic industrial chemicals, and toxic industrial materials. The diversity of equipment is advantageous, but it also presents a significant challenge because of the difficulty of directly comparing the instrument capabilities and assessing which detector best suits an organization's specific priorities. It is important to emphasize that the product summaries and evaluations in the guide are based solely on vendor-supplied information, and there is no process to verify that the equipment will perform as advertised. Several recent studies suggest that these goals are not being met. 4.5.6 In addition, a 2011 MITRE Corporation study for the Chemical and Biological Division, within the Department of Homeland Security Science and Technology Directorate (DHS S&T), identified 339 different sensors. The study attempted to rank the sensors but had limited success due to the lack of independent data that could be correlated (false alarm rates, sensitivity, reliability, etc.) from the various vendors. To help guarantee the safety of the public, incident response personnel, and warfighters, chemical detectors must function as advertised and meet key performance requirements. Moreover, users must have complete confidence that the equipment provides accurate and reliable information.

The development of chemical detection performance standards has three primary areas of focus:

• Responders must have confidence in chemical detectors that meet the standard.

- Industry requires an equitable means to demonstrate that products meet responders' needs.
- Vendors require a means to test new technologies and compare capabilities.

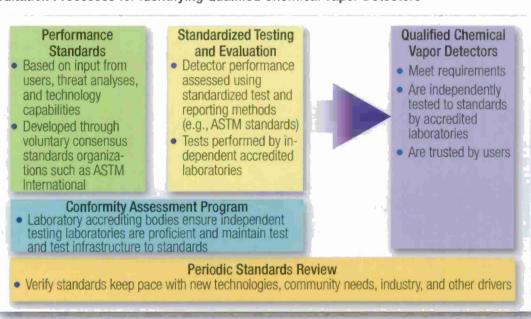
When underperforming products are potentially dangerous or place people at risk, a standards-based conformity assessment process can provide an effective method to ensure that quality detection equipment performs as required. ⁷ To that end, the National Science and Technology Council's Committee on Homeland and National Security recently published A National Strategy for CBRNE Standards⁸ that describes the federal vision to create a comprehensive structure for the coordination, establishment, and implementation of chemical, biological, radiological, nuclear, and explosives (CBRNE) equipment standards by 2020.

Consensus Performance Standards

Voluntary consensus standards (VCS) for chemical detector performance define measurable system attributes that strike a balance between user requirements, threat and risk assessments, and technological capabilities. The DHS Chemical Detection Standards Subject Area Working Group coordinates information gathering from a variety of sources, including on-the-ground responders, responder leadership, subject matter experts, detector manufacturers, and federal funding sponsors. The DHS Chemical Security Analysis Center provides threat and risk assessments, while the DHS S&T Chemical and Biological Division assesses both state-of-the-art and potential next-generation detector capabilities. Figure 1 outlines the specific standards needed to verify the performance of chemical detectors through quality-assured independent laboratory testing.

FIGURE 1. Performance Standards, Test and Evaluation Standards, and Laboratory Accreditation Processes for Identifying Qualified Chemical Vapor Detectors

Customer Needs Responders need confidence in commercial chemical detectors Industry requires fair process to demonstrate products meet responders' needs Vendors require means to test new technologies and compare capabilities



The process of collecting and distilling input from the large number of diverse federal, state, and local responder communities is difficult. Currently, the majority of the requirements are identified, as needed, through meetings and workshops with a limited number of responder communities. Several, more formalized avenues for gathering information from the user communities are also being tapped, including the following:

- InterAgency Board for Equipment Standardization and Interoperability, which maintains the standardized equipment list for CBRNE equipment
- DHS S&T Capstone Integrated Product Teams for First Responders and for Chemical/Biological Defense, which consist of DHS customers and key stakeholders
- International Association of Fire Chiefs, which provides a discussion forum for first responders
- Department of Defense (DoD) Joint Requirements Office capability design documents.

VCS performance standards are being developed and disseminated through ASTM International. Currently, ASTM E2411-07, "Standard Specification for Chemical Warfare Vapor Detector," specifies the criteria for CWA point detectors. ASTM E2411-07 addresses equipment for a wide range of applications, including four operational modes (personal, fixed installation, vehicle mounted, and survey detectors), and follows a onesize-fits-all approach. A new set of performance standards, based on ASTM E241I-07 and recent DoD detector performance specifications, but aligned more directly to specific operational scenarios and current federal priorities, is being developed. ASTM work product 33681, "The Standard Specification for Handheld Point Chemical Vapor Detectors (HPCVD) for Homeland Security Applications," has been developed by a joint team from DHS, the National Institute of Standards and Technology (NIST), DoD, and MITRE, with input from the detector community. A significant benefit of using VCS bodies is that they have an established and required periodic review of all standards, enabling the community to address dynamic threats, changing technologies, and evolving operations.

The HPCVD performance standard addresses a wide range of detector properties, including general attributes, such as size, weight, power, and reliability, and technical capabilities, such as chemicals detected, sensitivity, response time, and false-alarm rate. The technical capabilities included in the new performance standard are based on healthbased recommendations developed by the National Advisory Committee for the Development of Acute Exposure Guideline Levels (AEGL) for Hazardous Substances.9 The AEGL values provide guidance for short-term exposure scenarios, such as accidental chemical spills that can involve the general public, including the elderly, children, and other individuals who may be more susceptible to injury or death. AEGL values are primarily based on acute toxicology data, rather than on subchronic or chronic data, and the values identify varying threshold exposure concentrations and exposure times associated with toxic effects with varying degrees of severity. Within this framework, end users can identify priority chemicals and detection levels based on their specific operations. Similarly, vendors will be able to state specific detector capabilities related to the target AEGL detection goals. These vapor concentrations also define the test criteria for the evaluation program.

Performance requirements beyond the chemical and chemical concentration that triggers an alarm affect the design and functionality of chemical detectors. The other technical properties included in the HPCVD performance standard are detector response time, clear downtime, detection success rate, mean time between false alarms, and so on, Environnental factors often affect readings from chemical detectors; therefore, operating conditions such as the ambient temperature, relative humidity, and pressure ranges are specified in the performance standard. Nontoxic and relatively benign chemical vapors that might be present in the ambient atmosphere can also modulate a chemical detector's response to threat compounds, causing the detector either to miss the presence of a toxic material (a false negative alarm) or to alarm when toxic materials are not present (a false positive alarm). Overall, the HPCVD performance standard defines the operating ranges and performance criteria to which a detector must conform to be certified to the ASTM standard.

Standards-Based Test and Evaluation

Standardized test methods and reporting ensure that independent equipment evaluations are properly designed to guarantee that

- the procedure actually tests the intended property,
- the tests with validated materials are uniform, and
- the results are reported in a standard manner to facilitate data interpretation and comparisons.

If these conditions are met, the results of testing a given detector at one accredited laboratory will agree with the results from similar tests executed at another accredited laboratory. The testing protocols must include sufficient detail to eliminate any potential ambiguities and allow technically competent individuals to reproduce the tests and results in different laboratories. Reference methods, materials, and data must be available, because they are key tools used by testing personnel to establish and maintain equivalent measurements. Periodic interlaboratory comparisons should be executed to help verify

that results from different testing laboratories are equivalent and remain comparable over time.

The number of chemicals and the vapor concentration ranges of interest make chemical detector testing a complex and costly endeavor requiring a significant amount of laboratory infrastructure. Laboratories certified to handle toxic industrial chemicals and CWAs must be able to deliver, to the detector being tested, the correct chemical vapor concentrations at operationally relevant temperatures, relative humidity levels, and pressures and with common background chemicals at appropriate concentrations. The currently certified CWA test facilities have developed a variety of test plans, standard operating procedures, and reports describing their capabilities and procedures. These reports provide a foundation for building ASTM guides and practices. NIST has also developed a small-scale chemical detector test capability to facilitate the standards development process and to help establish the comparability of measurements throughout the testing communities. "Cut and dried" verification and evaluation of other detector attributes, such as reliability, electromagnetic compatibility, and environmental hardness, must occur along with chemical testing. Several ASTM and DoD specifications apply to each of these ruggedness attributes, which will be cited as appropriate in the final detector test and evaluation standard.

Conclusion

A joint team from DHS, NIST, DoD, and MITRE has moved forward on the development of consensus standards to meet the needs of first responders, per *A National Strategy for CBRNE Standards*. The establishment of performance standards, test methods, testing laboratory requirements, reporting methods, and accredited testing laboratories will provide the infrastructure needed to ensure that commercial chemical detectors conform to standards and satisfy mission requirements. "The Standard Specification for Handheld Point Chemical Vapor Detectors for Homeland Security Applications (HPCVD)" is currently in ASTM balloting as the initial voluntary consensus standard. The test results will be reported in a standardized format, enabling federal, state, local, tribal, and territorial agencies to make more informed procurement decisions through direct comparisons of independently demonstrated equipment capabilities.

About the Authors

Pamela Chu, PhD, is a research chemist at the National Institute of Standards and Technology with more than 20 years of experience In gas metrology. Dr. Chu is the task leader for the chemical standards for ASTM Committee E54.01 CBRNE Sensors and Detectors for Homeland Security Applications.

Charles Laljer is a senior systems engineer at MITRE Corporation, with over 20 years of experience with CBRNE equipment. Mr. Laljer is the chief engineer of the DoD Joint Chemical Agent Detector.

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²National Institute for Occupational Safety and Health, NIOSH Pocket Guide to Chemical Hazards, 2011.

³Department of Homeland Security, Guide for the Selection of Chemical Detection Equipment for Emergency First Responders, 3rd ed. Guide 100-06, 2007.

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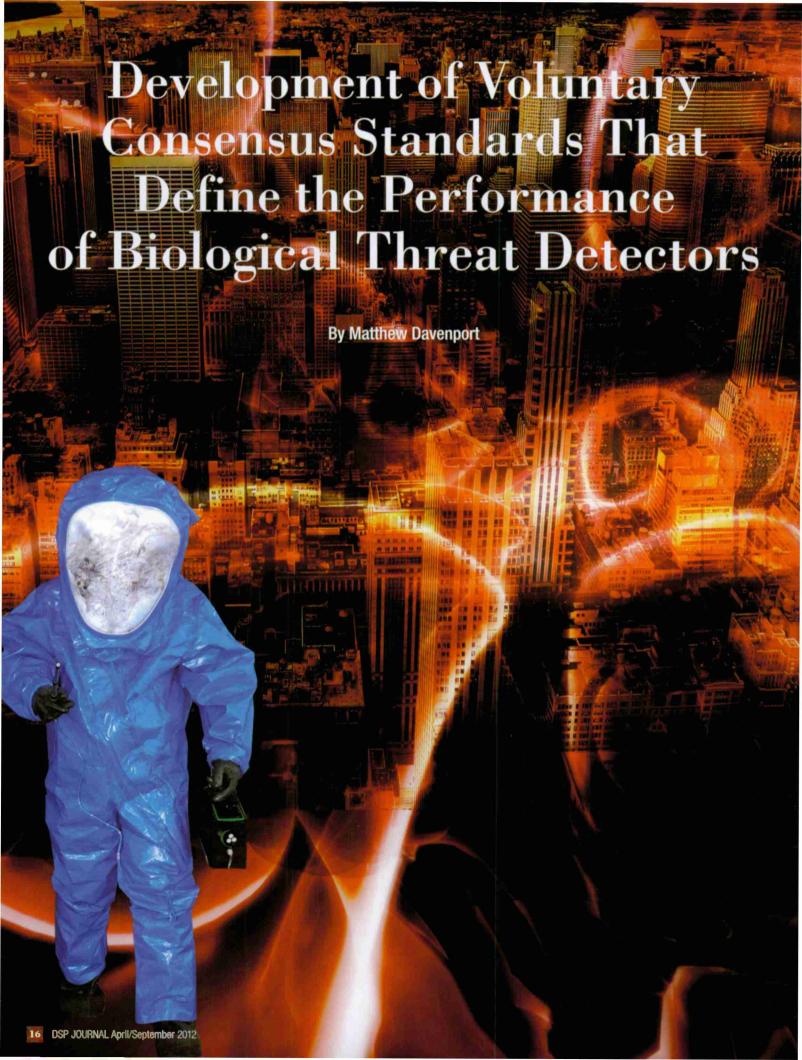
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⁷G. Gillerman, "Making the Confidence Connection," ASTM Standardization News, 2004.

⁸ National Science and Technology Council, Committee on Homeland and National Security, A National Strategy for CBRNE Standards, 2011.

⁹Committee on Acute Exposure Guideline Levels, Committee on Toxicology, and National Research Council, Acute Exposure Guideline Levels for Selected Airborne Contaminants, Volume 9 (The National Academies Press, 2010).



In the last decade, there has been a proliferation in the development, manufacture, sale, and fielding of detectors that screen suspicious samples for the presence of biological threat agents (biothreats). These detectors include field-based tools purchased and used by first responders to protect the public and detectors employed by private-sector entities (e.g., airports, hotels, and financial institutions) to protect their infrastructure and maintain business continuity. For the purpose of this article, the term "detector" is used to encompass biothreat detection systems, technologies, tools, and assays.

In contrast to the increase in the number of detectors available for purchase, there has not been a concomitant increase in the development of consensus standards to define how they should perform in the hands of end users. These consensus performance standards include detection performance requirements the detector should meet or surpass (e.g., probability of detection, sensitivity, and specificity), the panels of reference materials the detector is tested against (e.g., inclusivity and exclusivity panels), and the test protocols used in third-party testing. Likewise, there have been limited third-party testing and certification of detectors to demonstrate that they meet or surpass performance requirements outlined in consensus standards.

These consensus performance standards are necessary to define how biothreat detectors should perform in third-party testing and, more important, in the field to enable the end user to take appropriate response actions in the event a biothreat is detected. Stakeholders from the biothreat detection community have articulated a need for these standards, as well as third-party testing and certification, in multiple forums and in numerous publications, including National Strategy for CBRNE Standards published by the White House² and Framework for a Biothreat Field Response Mission Capability published by the Department of Homeland Security (DHS).3

Although the need to develop consensus performance standards is well recognized, their development over the past decade has been slow and difficult due to a number of important issues. This article discusses two of the issues that must be considered when developing performance standards for biothreat detectors purchased and used by first responders. Further discussion will focus on efforts to develop these standards, as well as proposed next steps to address gaps in standards development and in testing and certification.

Critical Considerations for Developing Biothreat Detection Performance Standards

Developing consensus standards that define performance requirements for biothreat detectors is complicated by a number of factors, including the diversity of the stakeholder community and the complexity of the biothreat. These two factors deserve critical consideration in order to develop relevant standards.

DIVERSE STAKEHOLDER NEEDS

Guidance on the development of standards is provided in the National Technology Transfer and Advancement Act (NTTAA)⁴ and Office of Management and Budget (OMB) Circular A-119.5 A critical element in developing voluntary consensus standards is inclusion of all stakeholders who have a material interest in the development of the standard in an open, transparent, documented process. Their inclusion and transparency of the process further the development of standards relevant to the intended use and the acceptance of the standards by a broad majority of the stakeholders.

Development of biothreat detection performance standards must consider the needs of a diverse community of stakeholders who have their own relevant needs. Balancing their needs appropriately can be complex. As an example, consider the development of consensus performance standards for detectors used by first responders in the field. The stakeholders who have an immediate interest in these standards are the response community that includes all those involved in the response to a suspicious sample. This community is diverse and includes stakeholders that appear to have competing needs in terms of the level of risk they will take in responding to an incident. ASTM E2770-10, "Standard Guide for Operational Guidelines for Initial Response to a Suspected Biothreat Agent," lists the stakeholders who should be involved in planning for, and responding to, such an incident.6 Stakeholders include first responders who purchase and use the detectors to make tactical decisions to manage an incident, as well as state and local public health officials who will be accepting a sample into the Centers for Disease Control Laboratory Response Network for confirmatory testing and possible public health response. Each stakeholder has a mission to protect the public (i.e., public safety and public health, respectively), and each community needs to be at the table to ensure their mission needs are represented by any resulting standard and the test and evaluation (T&E) and certification process.

In addition to the response community, stakeholders should be included from the community of those who develop biothreat detectors. This community includes industry. Industry stakeholders are keenly aware of the capabilities of current and future technologies and can weigh in on whether or not a standard is applicable to technological capabilities. In addition, this community is often experienced in development of clinical diagnostics and the cost of testing involved in approval by the Food and Drug Administration. This experience provides valuable perspective on whether or not the amount of testing resulting from the performance standards is cost-effective.

COMPLEXITY OF THE BIOTHREAT

In addition to involvement of the stakeholders discussed above, involvement of subject matter experts who have the most current scientific understanding of the biothreat and how that relates to detection is critical. Biothreats represent complex analytes whose biology can make them difficult to reliably detect in the field. This complexity is demonstrated in at least four ways.

First, a biothreat is often not one threat, but a "family" of pathogens, any one of which could be used in an act of biological terrorism. For example, Bacillus authracis, the causative agent of anthrax, is not a single biothreat; rather, it is a species of organisms, which includes more than 200 individual strains that are human pathogens.⁷ These strains differ at a genetic level, differences that may affect the ability to detect each strain. A B. anthracis detector must be able to detect a representative panel of these potential pathogens (i.e., an inclusivity panel) to reduce the likelihood that an important strain will go undetected, thereby leading to a false-negative result in the field.

A second complexity is the fact that biothreats typically have nonthreat near neighbors in the environment whose biology is similar to that of the real threat. Due to this similarity, the nonthreat may be detected inadvertently. For example, B. anthracis has a number of near-neighbor species and strains that are genetically similar and found in the environment (e.g., B. cerens, B. thuringeiusis, and B. subtilis). A detector for B. anthracis should not detect members of a representative panel of these species and strains (i.e., exclusivity panel). To do so would lead to a false-positive detection in the field.

The third complexity is that differentiation between a threat and a nonthreat is not always obvious. Using B. authracis as the example again: there are strains of B. cereus, typically considered a genetic near neighbor, that harbor pathogenic elements and can cause disease in some circumstances. These strains of B. cereus could be considered examples of inclusivity or exclusivity, depending on the intended use of the detector.

The last complication is the fact that our scientific understanding of the biology of the threat and the diversity of organisms (threats and nonthreats) in the environment is often limited, though rapidly evolving. There are certainly organisms not yet identified that may be important threats for detection or important near neighbors that should not be detected.

The complexities discussed above point to the critical need for the standards development process to include stakeholders who perform leading-edge research on the biothreat of interest. These experts, working with the other stakeholder communities, must bring the most up-to-date and best-available science to the standards process to perform two critical tasks. The first task is to determine the scientific rationale by which inclusivity and exclusivity species and strains should be chosen. The second task is to use the criteria to choose species and strains that will be used in third-party testing of the detector. Thoughtful selection of the criteria and strains is needed to ensure that the detector performance is fit for its intended use as defined by the response stakeholders discussed above, while at the same time, ensuring that the cost of testing is not overly burdensome in order to incentivize industry to participate in testing.

It should be noted that the examples above considering B. anthracis as the biothreat are relatively straightforward because B. anthracis is a well-studied and genetically monomorphic organism. The need for best-available science for establishing selection criteria and strains becomes more critical when considering standards for organisms that evolve rapidly or are hyperplastic (viruses whose genomes are made up of ribonucleic acid and Burkholderia psnedomallei, respectively) or whose biology is less well understood.

Standards Development Efforts to Date

Efforts to develop biothreat consensus performance standards have evolved over the past decade. The largest consensus effort to date involves the establishment of the Stakeholder Panel on Agent Detection Assays (SPADA) by AOAC International, under the funding of the DHS Science and Technology Directorate (S&T). SPADA is a voluntary consensus standards body of more than 100 volunteer stakeholders from federal, state, and local governments; the first-response and public health communities; academia; and industry. SPADA's mission is to develop consensus performance standards (also known as Standard Method Performance Requirements, or SMPRs) that define the performance criteria the detector should meet or surpass (e.g., probability of detection, sensitivity, and specificity) and the reference material panels against which the detector should be tested (e.g., inclusivity, exclusivity, background, and interferents).

When SPADA was established in 2007, its mission was to develop SMPRs for biothreat detectors that screen aerosol collection samples for Francisella tularensis, 10 Yersinia pestis, 11 or B. anthracis, 12 using polymerase chain reaction (PCR) technology. This effort was intended to develop standards and a test methodology for detectors employed by privatesector entities. In 2009, SPADA incorporated past work funded by DHS S&T to develop SMPRs and test immunoassay-based handheld assays used by first responders to screen suspicious powders for ricin¹³ or B. anthracis. ¹⁴ In 2010, SPADA began work on two additional standards development efforts. The first was development of SMPRs for detectors that use PCR to screen aerosol collection samples for Burkholderia psuedomallei15 and Burkholderia mallei. 16 The second was development of SMPRs for portable devices that screen suspicious powders for B. anthracis using PCR rather than immunoassays. 17 To develop each SMPR (e.g., SMPR 2010.001), SPADA considered the needs of the response community, the best-available science of the biothreat, the capabilities of the detection technology, and the cost of the testing. All SPADA activities were consistent with NTTAA and OMB Circular A-119; they were open to the entire SPADA membership and documented. From those activities, eight SMPRs have been developed; five are published in open literature. SPADA continues its work currently in consideration of performance standards for detectors that screen aerosol collection samples for Variola, the causative agent of smallpox.

In addition to the considerations above, SPADA considered one other critical issue when establishing reference material panels: the availability of the reference material. For example, there were strains of Burkholderia species identified in published scientific literature; however, they were not available for general access for testing purposes. Strains that will not be distributed by the owner cannot be included in reference material panels, because this creates a requirement that cannot be achieved on the development and T&E of a detector.

The primary function of the performance standards developed by SPADA is to serve as requirements for development of test protocols for third-party testing and certification of detectors. In conjunction with the standards development efforts of SPADA, DHS S&T funded Idaho Technology, Inc., and MRIGlobal to work with AOAC and SPADA to pilot test a third-party T&E of the RAZOR EX to the standards outlined in SMPR 2010.003. This activity led to the certification of the RAZOR EX B. anthracis detector as an AOAC Performance Tested MethodSM. 18

Ultimately, tools that pass testing against the standards and receive certification can be targeted for purchase by end users. In addition to their use in T&E, the SPADA standards have at least two other impacts. First, the standards provide guidance to detector developers on the development of new detection technologies that meet the needs of first responders and public health. Second, the standards can serve as minimum performance standards that can be used by federal T&E programs. Federal agencies can leverage the work of SPADA by using all or part of the SMPRs and add mission-specific requirements to meet their needs.

Conclusion

The development of consensus performance standards requires the involvement of all stakeholders who will be affected by the standard. In terms of standards that define performance of biothreat detectors used by first responders, those stakeholders include first responders, public health professionals, law enforcement, and federal agencies that support response. The standards also affect industry and other detector developers and manufacturers, because this community will be expected to develop tools that meet the standards. In addition to these stakeholders, subject matter experts who research the biology of the biothreat are required in the process to ensure that the best-available science is incorporated into the resulting performance standards.

SPADA has developed a number of performance standards (SMPRs) that define the expected performance of detectors that screen aerosol collection samples and suspicious powders for a number of biothreats. The performance standards developed by SPADA are one piece necessary to demonstrate that a biothreat detector meets the needs of the community of end users and responders. Future efforts need to consider operational standards (ruggedness, time to detect, and so on) and field T&E to ensure the detector works in the field in the hands of the end user.

Prioritization of future performance standards development and testing and certification of biothreat detectors should focus on the needs of the first-response community. Across the nation, first responders are called daily to address suspicious samples that may be a biothreat. A biothreat detector is a critical tool that gives responders the ability to make tactical decisions to protect themselves and the public during these incidents. To manage these incidents and make appropriate decisions, responders require detectors that are tested by a third party and certified to meet or surpass performance requirements outlined in recognized voluntary consensus standards. Certified detectors can be targeted for purchase by responders using their limited funding and enable the activities of all stakeholders involved at all levels of response as described in ASTM E2770-10.

¹Defense Threat Reduction Agency, Department of Defense, Chemical, Biological, Radiological Technology Survey, P. Emanuel and M. Caples (Eds.), 2011.

²National Science and Technology Council, Committee on Homeland and National Security, A National Strategy for CBRNE Standards, 2011.

See https://www.rkb.us/contentdetail.cfm?content_id=270212.

⁴National Technology Transfer and Advancement Act of 1995.

⁵Office of Management and Budget, Federal Participation in the Development and Use of Voluntary Consensis Standards and in Conformity Assessment Activities, Circular A-119, 1998.

⁶ASTM E2770-10, "Standard Guide for Operational Guidelines for Initial Response to a Suspected Biothreat Agent" (West Conshohocken, PA: ASTM International, 2010), Section 6.

⁷P. Keim et al., "The Genome and Variation of Bacillus authracis," Molecular Aspects of Medicine, Vol. 30, No. 10 (2009), pp. 397–405.

⁸S.B. Avashia et al., "Fatal Pneumonia Among Metalworkers Due to Inhalation Exposure to *Bacillus cereus* Containing *Bacillus anthracis* Toxin Genes," *Clinical Infectious Diseases*, Vol. 44, No. 3 (2007), pp. 414–416.

S.G. Coates, S.L. Brunelle, and M.G. Davenport, "Development of Standard Method Performance" Requirements for Biological Threat Agent Detection Methods," Journal of AOAC International, Vol. 94, No. 4 (2011), pp. 1328-1337.

¹⁰SMPR 2010.001, "Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of Francisella tularensis in Aerosol Collection Filters and/or Liquids," Journal of AOAC International, Vol. 94, No. 4 (2011), pp. 1338-1341.

¹¹SMPR 2010.002, "Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of Yersinia pestis in Aerosol Collection Filters and/or Liquids," Journal of AOAC International, Vol. 94, No. 4 (2011), pp. 1342-1346.

¹²SMPR 2010.003, "Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of Bacillus authracis in Aerosol Collection Filters and/or Liquids," Journal of AOAC International, Vol. 94, No. 4 (2011), pp. 1347-1351.

¹³SMPR 2010.003, "Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of Bacillus anthracis in Aerosol Collection Filters and/or Liquids," Journal of AOAC International, Vol. 94, No. 4 (2011), pp. 1347-1351.

¹⁴SMPR 2010.004, "Standard Method Performance Requirements for Immunological-Based Handheld Assays (HHAs) for Detection of Bacillus anthracis Spores in Visible Powders," Journal of AOAC International, Vol. 94, No. 4 (2011), pp. 1352-1355.

¹⁵SMPR 2011.001, "Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of Burkholderia psuedomallei in Aerosol Collection Filters and/or Liquids," Journal of AOAC International, 2012 (in preparation).

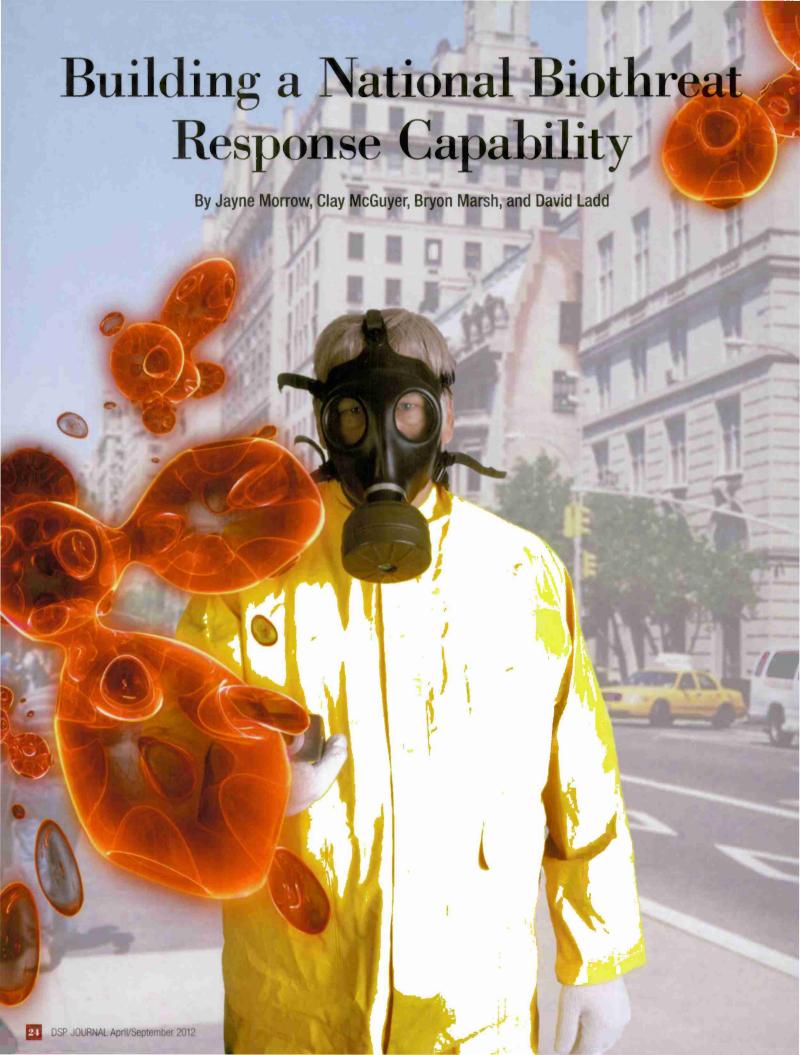
¹⁶SMPR 2011.002, "Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of Burkholderia mallei in Aerosol Collection Filters and/or Liquids," Journal of AOAC International, 2012 (in preparation).

¹⁷SMPR 2011.003, "Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of Bacillus anthracis Spores in Visible Powders," Journal of AOAC International, 2012 (in preparation).

¹⁸U.K. Spaulding et al., "RAZOR EX Air Detection System," Journal of AOAC International, Vol. 95, No. 3 (2012), pp. 860-891.

About the Author

Matthew Davenport, PhD, is acting program manager, Biological Defeat Technologies, at the Johns Hopkins University Applied Physics Laboratory and the current chair of SPADA. Previously, he was a program manager at DHS S&T where he established the DHS Public Safety Actionable Assay program and SPADA to develop voluntary consensus standards for the validation of biothreat detection technologies used by first responders and private-sector end users. In addition, Dr. Davenport coordinated a number of bioinformatics efforts, such as the development of new databases and software to identify signatures that can be used to specifically detect biothreat agents, sequencing strains of biothreats and their genetic near neighbors, and application of next-generation sequencing to biothreat detection.



In May 2011, the Obama administration released A National Strategy for CBRNE Standards, which presents six goals to foster the interoperability of equipment and standards to be used when responding to chemical, biological, radiological, nuclear, and explosive (CBRNE) incidents. Goal 4 calls for CBRNE standard operating procedures (SOPs), and Goal 5 calls for the establishment of voluntary CBRNE training and certification standards. Common SOPs for strategic, operational, and tactical coordination are required for a successful response and informed decision making. Existing SOPs related to identifying, handling, and responding to hazardous chemical, biological, and radiological threats form the baseline for developing new SOPs for CBRNE detection, protection, and response. The communication and integration of SOPs nationally is critical to establishing an interoperable response capability.

Shortly before the administration released the national strategy, the Department of Homeland Security (DHS) released Framework for a Biothreat Field Response Mission Capability, which was developed by an interagency working group.2 The framework document, which directly supports Goals 4 and 5 of the national strategy, and the process used to develop the framework constitute a model for establishing national SOPs—referred to here as a concept of operations (ConOps)—and integrating those SOPs into training programs.

This article highlights the framework's support of Goals 4 and 5 of the national strategy and then elaborates on key gaps to building a successful national biothreat response capability.

Overview of the Framework

The framework document's specific purpose is to provide guidance to first responders for assessing powders suspected of being a biological hazard. The framework identifies five critical elements for ensuring mission capability:

- 1. A ConOps to support use of field assays and coordination of response among the key stakeholders in the jurisdiction
- 2. Training and certification of end users
- 3. Proficiency testing in the hands of the end user in the field
- 4. Sample collection
- 5. Assays that have been properly tested by a qualified third party and certified to meet or exceed national voluntary consensus standards for performance.

To date, significant progress has been made on the first, fourth, and fifth elements. The first critical element, a ConOps, was addressed through the publication of ASTM E2770-10, "Standard Guide for Operational Guidelines for Initial Response to a Suspected Biothreat Agent." These consensus operational guidelines establish how a hazardous materials (HazMat) response team or a specialized CBRNE response team, such as a National Guard Weapons of Mass Destruction—Civil Support Team (WMD-CST), would provide an incident commander (IC) with a risk assessment, including a hazard assessment and threat evaluation accomplished through screening the suspected material associated with sample collection.

A coordinated risk assessment would determine the best course of action for the IC, including characterization regarding the general hazard, the decision to collect a sample, and the best way to safely transport samples to the Centers for Disease Control and Prevention's (CDC's) National Laboratory Response Network (LRN) for confirmatory testing and analysis. The risk assessment includes a threat evaluation done in conjunction with law enforcement, and preferably led by the Federal Bureau of Investigation (FBI) WMD coordinator, to assess the credibility of the threat, as described in ASTM E2770–10. The threat evaluation would determine the context of the incident, such as the presence of a threatening communication or victims with signs and symptoms of a biological infection.

In addition to working in consultation with the FBI, the IC should work with the local public health LRN representative. If the IC determines that the threat is credible or that the absence of a hazard needs to be confirmed (for risk communication purposes), then samples should be collected according to the procedures defined in ASTM E2458-10, "Standard Practices for Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biological Agents from Nonporous Surfaces." These consensus standards on sample collection provide for splitting the samples: the bulk of the suspicious material is collected by "Method A" and submitted to the LRN for rapid presumptive and confirmatory testing; the remainder is collected by "Method B" for on-site biological assessment, with field testing by the CST mobile analytical laboratory suite or by a HazMat team. The fifth element listed provides for national consensus performance standards that define the minimum performance requirements needed for on-site field testing.

The five critical elements of the biothreat field response mission capability provide a template for implementing standardization in interagency functional support across the elements of CBRNE. Other functional response capabilities lacking standardization could benefit from using this approach to integrate standardized procedures, standardized equipment, operator training and certification, and training sustainment through proficiency testing and retraining, all integrated into a ConOps. A concerted effort in standardization over many years can lead to evolutionary changes, similar to what happened when the Emergency Medical Services (EMS) system was implemented in the late 1960s. In the EMS community, technology, methods, and accrediting organizations trans-

formed the ambulance from simple transport to an extension of the emergency room. HazMat teams, and their military counterparts, are also transforming, becoming the field response units for the state public health laboratory to support the framework for a biothreat field response mission capability.

Integrated Federal, State, and Local Response

In 1998, President Clinton announced that the United States would do more to defend against acts of terrorism involving biological and chemical warfare agents. That announcement resulted in the creation of the National Guard WMD-CST program with the specific mission of helping local authorities with incidents involving WMD. The program now has 57 WMD-CSTs dispersed across Federal Emergency Management Agency (FEMA) regions. The success of the CST program has led to the continued growth of the National Guard's CBRNE mission, which now makes up the bulk of the U.S. military's CBRNE response force. DoD has recently expanded capabilities in the National Guard to support CBRNE response in every state and territory. These capabilities include CBRNE "Enhanced Response Force Packages" and "Homeland Response Forces."

As federal, state, and local authorities have worked to assemble a capable CBRNE enterprise for response to terrorism, challenges have arisen on how to integrate these capabilities into a wholeof-government response framework.

Outside DoD, many other capabilities have also evolved. Local civilian response teams have proliferated, including teams with specialized capabilities to support suspicious powder events and other terrorist threats. Standardization and sustainment of local capabilities have been challenged by fiscal constraints and a lack of national standards for response until the recent publication of ASTM E2770-10. Despite these challenges, large local jurisdictions and many state-level organizations have successfully developed and maintained specialized suspicious powder response capabilities. These national best practices were pulled together in the standard guidance for a suspected biothreat ConOps and published in ASTM E2770-10. ASTM E2770-10 focuses on coordinating the initial response to suspected biothreats with the first responders, public health laboratories receiving samples, and law enforcement. The ConOps recommended by these stakeholders covers (1) response planning, training, and protocol development; (2) coordination of the

approach to and timing for collecting a sample; (3) sample collection method and packaging; and (4) transport and submission of a sample to a reference laboratory in the CDC LRN for confirmatory testing. The CDC LRN is the public health laboratory network responsible for handling clinical specimens and environmental samples containing suspected biothreat agents. Federal civil agencies, including the CDC, FBI, Environmental Protection Agency, and others, have established programs to support the federal response to terrorism.

As federal, state, and local authorities have worked to assemble a capable CBRNE enterprise for response to terrorism, challenges have arisen on how to integrate these capabilities into a whole-of-government response framework. The stakeholders recognize that integrating all aspects of a response is fundamental to improving national preparedness and is the driving force behind the national strategy for developing CBRNE consensus standards.

Training at the State and Local Levels

Operational exercises and other training events provide a mechanism for giving the participants unique insight into effective coordination and communication in a real-world scenario. In collective training exercises, all stakeholders—including law enforcement, public health, and public safety personnel—bring their unique skills and perspectives together to develop an effective integrated response capability.

An integrated training approach has been developed with Fort Detrick's Biological Agent Identification and Counterterrorism Training (BAIT) center. BAIT offers the opportunity for first responders to train with their CST in a challenging training lane that includes laboratory testing, often coordinated with the LRN, of collected samples. Over the past several years, DHS, the FBI, the National Institute of Standards and Technology, state public health agencies, law enforcement agencies, and the WMD-CST have collaborated in Operation Vigilant Sample (OVS) to conduct a collective training event that exercised all stakeholder roles for response to a suspicious powder. The OVS goal is to exercise the IC's role in determining the need to collect and submit samples to the state's public health laboratory through a law enforcement lead threat evaluation with a local responder and CST hazard assessment.

Currently, in responding to a suspected biothreat agent, all the key components of an exercise are built around the standardized sampling collection and ConOps procedures, ASTM E2458-10 and E2770-10, respectively. ASTM E2770-10 provides the ConOps for the response with guidance on how to collectively arrive at the decision to submit a sample for confirmatory testing. OVS provides an opportunity to examine screening and the role of on-site biological assessment by both the HazMat team and a mobile laboratory such as the CST mobile analytical laboratory suite. Exercising the real-world coordination that includes a field on-site biological assessment of a collected Method B sample is an example of how the framework for a biothreat field response mission capability can work. The BAIT training lane was made possible because of a substantial commitment on the part of DoD to field these resources to the community.

Collective training events, like the OVS, that use standardized sample collection and ConOps provide a means to study how standards are being integrated, as well as to evaluate the efficacy of communication and coordination practices for preservation of public safety and public health in a real emergency. Three key lessons have been learned from training events:

- Sampling teams must train with local public safety and public health professionals.
- The training events should exercise every link in the chain, from sample collection through analysis.
- The training events should ideally be available at local venues.

Recent training exercises also have led to questions about whether decontamination procedures could inhibit detection in the laboratory:

- How quickly can a public health determination be made in an urban versus rural environment?
- How can laboratory processes be optimized based on the expectation of a standardized sample arriving from the field?

These serious questions can be evaluated most effectively during collective training events in which all of the stakeholders actively participate in real-time decision making. In scenarios as serious as a potential anthrax letter attack, contamination, delayed results, or analysis problems could all result in dire consequences: the loss of human lives.

Collective Training Events and Exercises

The austere environment that local governments face today can be a hurdle to implementing the framework for a biothreat field response mission capability. Currently, many state and local jurisdictions achieve training goals through individual training programs offered by DoD, including Dugway Proving Ground; FEMA training organizations, such as those in the National Domestic Preparedness Consortium; regional training events (including those offered by the International Association of Fire Chiefs, Midwest Hazardous Materials Response Conference, and the HOTZONE); and independent training organizations. However, only a small fraction of the responders at state and local jurisdictions can attend off-site training opportunities due to fiscal constraints, limited capacity of training venues, and challenges covering vacancies while responders attend training,

therefore limiting the ability to establish a comprehensive national biothreat response capacity. Furthermore, no federal agency or national organization has stepped forward to serve as the training and accreditation body for individual training of first responders. In addition, attrition and the need for recurrent training create an ever-expanding need for training that cannot be met by national or even regional centers.

Some of these challenges can be partially addressed through collective training exercises combined with individual training. Collective training lanes can be expanded at the local level to better include all stakeholders in real-world scenarios critical to building a proven field capability. Jurisdictions can establish a biothreat field response capability by developing a ConOps according to ASTM E2770–10; developing a strong base of individual training on standardized sample collection, packaging, and transportation procedures; and implementing the standardized procedures through a local collective exercise venue.

The simplicity and straightforward equipment requirements recommended in ASTM E2458-10 enable widespread adoption and utilization of the ConOps and the collection procedures within the CBRNE training community for response to suspected biothreats. Regional/local collective training venues could support delivering training locally and on demand to meet changing threats. Once collective training using the standardized procedures—essential to building a national biothreat field response mission capability has proliferated, these types of training events can be used to sustain skills and maintain proficiency of all the stakeholders over the long term. In the military, service members participate in routine training events yearly to ensure that they retain the critical skills they have learned but do not use every day. DoD uses yearly collective training events with great success so the Reserves and National Guard are prepared to serve when needed in places such as Afghanistan and Iraq. The same approach could be used to maintain the skills of sampling teams, public safety personnel, and public health personnel to provide critical capabilities when needed to save lives here in the United States. Future efforts focused on integrating military and civilian response capabilities in a uniform ConOps will need to determine the feasibility and cost/benefit relationship of collective training. However, the civilian first-responder community could benefit greatly from having better access to DoD training opportunities, and sharing training and evaluation resources with local communities can, in turn, enhance DoD's civil support of the CBRNE response mission.

¹See http://www.whitehouse.gov/sites/default/files/microsites/ostp/chns_cbrne_standards_final_ 24_aug_11.pdf.

²See https://www.rkb.us/contentdetail.cfm?content_id=270212&query=framework%20for%20a% 20biothreat%20field%20response%20&overridesubtype=950.

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Jayne Morrow, PhD, a research engineer, leads the Biothreat Agent Detection and Sampling Program at the National Institute of Standards and Technology. Dr. Morrow's research has contributed to interagency efforts to enable effective response to and recovery from a biothreat incident across the federal government over the last 7 years. Recent efforts include supporting the development of ASTM E2770 and E2458, which provide guidance and sample collection methods, respectively, for initial response to suspected biothreat incidents.

Lieutenant Colonel Clay McGuyer, PhD. is the chief of Strategic Planning and Initiatives for the National Guard Domestic Operations and Force Development Directorate. He manages integration of National Guard capabilities with DoD and whole community response efforts, and he develops emerging requirements for the National Guard.

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David Ladd directs the Hazardous Materials Emergency Response Division, Massachusetts Department of Fire Services. He has led the Massachusetts statewide hazardous materials response system since 1999 and has served in various public safety and emergency medical services posts since 1974. The Massachusetts Department of Fire Services operates six regional hazardous materials response teams, providing comprehensive CBRNE response capabilities in close coordination with its LRN laboratory, bomb squad, and the 1st Civil Support Team. Mr. Ladd also serves on several national working groups and committees focused directly on bioterrorism response and is principally engaged in the development of standards cited in this article.

Status of the GRaDER Program



The Graduated Rad/Nuc Detector Evaluation and Reporting (GRaDER) program evaluates commercial off-the-shelf (COTS) radiological/nuclear detection equipment against national consensus standards adopted by the Department of Homeland Security (DHS), as well as Technical Capability Standards (TCSs). The program's goal is to identify radiation detection products that comply with consensus standards and satisfy DHS mission requirements. Testing is carried out by independent third-party laboratories. To ensure high-integrity test data, testing laboratories are undergoing a laboratory accreditation process under the National Voluntary Laboratory Accreditation Program (NVLAP). The laboratory accreditation process is used to confirm the laboratory testing capabilities and competence. Test results are going to be listed in the GRaDER Evaluated Equipment List. The test results may enable federal, state, local, tribal, and territorial agencies to make more informed radiological/nuclear detector procurement decisions.

GRaDER Instrument Standards and Compliance Levels

The GRaDER testing is based on the DHS-adopted consensus standards published by the American National Standards Institute/Institute of Electrical and Electronics Engineers (ANSI/IEEE). On the basis of those standards, the Domestic Nuclear Detection Office (DNDO) defined seven different instrument categories:

- Category I—Alarming Personal Radiation Detectors (PRDs), ANSI/IEEE N42.32-2006, "American National Standard Performance Criteria for Alarming Personal Radiation Detectors for Homeland Security."
- Category 2—Survey Meters, ANSI/IEEE N42.33-2006, "American National Standard for Portable Radiation Detection Instrumentation for Homeland Security."
- Category 3—Radionuclide Identifiers (RIDs), ANSI/IEEE N42.34-2006, "American National Standard Performance Criteria for Hand-Held Instruments for the Detection and Identification of Radionuclides."
- Category 4—Radiation Portal Monitors, ANSI/IEEE N42.35-2006, "American National Standard for Evaluation and Performance of Radiation Detection Portal Monitors for Use in Homeland Security."
- Category 5—Spectroscopic Radiation Portal Monitors, ANSI/IEEE N42.38-2006, "American National Standard Performance Criteria for Spectroscopy-Based Portal Monitors Used for Homeland Security."
- Category 6—Mobile and Transportable Systems, ANSI/IEEE N42.43-2006, "American National Standard Performance Criteria for Mobile and Transportable Radiation Monitors Used for Homeland Security." This standard includes backpack-type radiation detectors (BRDs). A new ANSI standard for BRDs (ANSI N42.53) is being developed to more specifically address the requirements of this type of instrument.

 Category 7—Spectroscopic Personal Radiation Detectors (SPRDs), ANSI/IEEE N42.48-2008, "American National Standard Performance Requirements for Spectroscopic Personal Radiation Detectors (SPRDs) for Homeland Security."

Because the ANSI/IEEE standards cover a large number of requirements, DNĐO defined four compliance levels for assessing instrument performance (see Table 1.)

Table 1. Definitions of Compliance Levels for Assessing GRaDER Instruments

Level	Definition
0	Test results are not yet available, or the DNDO evaluation is not completed. The instrument does not meet the minimum subset of the ANSI/IEEE standards for levels 1, 2, or 3 and instrument categories listed below. The instrument is found to have changed configurations since last tested. The instrument has been on the GRaDER Evaluated Equipment List for 4 years or more without retesting. Its GRaDER program attestation has expired.
1	The instrument is no longer in production, and production stopped 1 year or more ago. Instrument partially meets ANSI/IEEE standards and has demonstrated specified performance compared to selected key sections of the standards. Criteria for Level 1 are defined for each instrument category and can be found at http://www.dhs.gov/files/programs/gc_1218637329931.shtm.
2	Instrument fully meets ANSI/IEEE standards, unless otherwise exempted by the instrument category criteria listed at http://www.dhs.gov/files/programs/gc_1218637329931.shtm.
3	Instrument meets Level 1 and/or Level 2 criteria listed at http://www.dhs.gov/files/programs/gc_1218637329931.shtm and also satisfies the requirements of the applicable published government-unique TCSs. Several TCSs are under development but are not yet implemented into the GRaDER program.

National Voluntary Laboratory Accreditation Program

The NVLAP provides third-party accreditation to testing and calibration laboratories. NVLAP's accreditation programs are established in response to congressional mandates, administrative actions by the federal government, and requests from private-sector organizations and government agencies.

NVLAP operates an accreditation system that is compliant with ISO/IEC 17011, which requires that the competence of applicant laboratories be assessed by the accreditation body against all of the requirements of ISO/IEC 17025. The GRaDER program uses NVLAP Handbook 150, NVLAP Procedures and General Requirements, together with the program-specific NVLAP Handbook 150-23, NVLAP Radiation Detection Instru*ments.* For more details, see http://www.nist.gov/nvlap/.

DNDO uses several laboratories for testing instruments under the GRaDER program: Oak Ridge National Laboratory (ORNL), Pacific Northwest National Laboratory (PNNL), and Global Testing Laboratories (GTL) in conjunction with Savannah River National Laboratory (SRNL). These DNDO-accepted laboratories are in the process of becoming NVLAP accredited.

Test and Evaluation Protocols

Test and evaluation protocols were developed to provide additional information to the testing laboratories. The test and evaluation protocols provide data sheets for collection of test results obtained when testing radiation detection instruments against the ANSI/IEEE N42 standards for homeland security applications. These sheets were developed from data files originally used by ORNL's Technical Testing and Analysis Center for data reporting. Now they are being maintained by the National Institute of Standards and Technology (NIST) as part of the GRaDER program.

The test and evaluation protocols provide recommendations on the order in which the tests described in the ANSI/IEEE standards should be executed. They also give additional information on how the instrument output data files may be validated to meet the ANSI/IEEE N42.42 standard requirements. In addition, they provide modifications to the test requirements or test methods described in the ANSI/IEEE N42 series if issues are found that require immediate action (before the standard can be revised).

The test and evaluation protocols, as well as the data sheets, for the published ANSI/IEEE N42 standards for testing radiation detection instruments can be downloaded from http://www.nist.gov/pml/div682/grp04/ansieeen42.cfm.

Present Status

The first round of tests of COTS radiation detection instruments were performed under the GRaDER program. Testing was carried out at ORNL, PNNL, and GTL/SRNL. It included instruments provided by manufacturers, as well as government-owned COTS instruments. Three different instrument categories (PRDs, RIDs, and BRDs) were tested; these included seven models of PRDs, five models of RIDs, and two models of BRDs.

NIST worked with DNDO in the review and reporting of the GRaDER test results. The test results were reviewed against the standard requirements, the GRaDER compliance-level requirements, and the test and evaluation protocols additions and modifications. For each requirement listed in the respective ANSI/IEEE standard, the result of the test was assigned a grade: pass, fail, not required, or not implemented. Comments and observations were added to summarize the instrument response and failures.

Test results will be available on the password-protected GRaDER program Homeland Security Information Network Community of Interest and the Federal Emergency Management Agency's Responder Knowledge Base. A summary of the test evaluation results will also be available to authorized agencies, and the test report and DNDO evaluation report may be requested from DNDO through the GRaDER program. Release of test reports will be determined using published guidance, coordination with the manufacturer, and stipulations of law.

The results of these tests will be used in the revision of the ANSI/IEEE standards and improvement of the test and evaluation protocols.

For more information on the GRaDER program, see http://www.dhs.gov/files/ programs/gc_1218637329931.shtm.

About the Authors

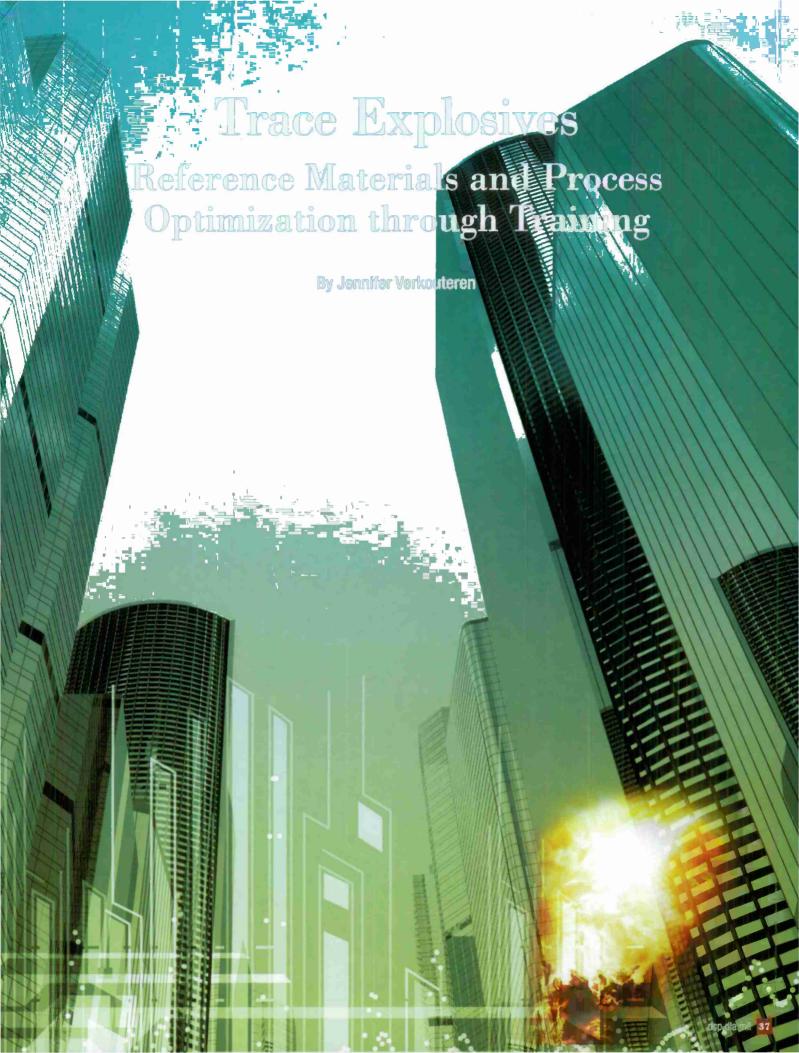
Leticia Pibida, PhD, is a nuclear physicist employed at NIST. She is the principal investigator for DHS rad/nuc projects, including GRaDER.

Cheri Hautala-Bateman, PhD, is the GRaDER program manager. In addition, she is a test scientist for DNDO's Systems Engineering and Evaluation Directorate. Previously, Dr. Hautala-Bateman was a scientist on various Department of Energy rad/nuc emergency response and radiological aerial survey teams.

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Explosives continue to be the weapons of choice for terrorists, both for use against civil aviation and other forms of mass transit and in improvised devices targeted against combat troops. The manufacture and transport of explosive devices leave microscopic traces that, if effectively detected, can identify bomb makers, carriers, and concealed devices. Screening technologies that detect traces of explosives are an important and effective tool against terrorism and are widely used by federal, state, and local agencies tasked with protecting the public. The National Institute of Standards and Technology (NIST) has a role in ensuring that these detection technologies operate as effectively as possible and that they continue to advance to meet the ever-changing threats.

Minimum Performance Standards

The majority of explosive trace detectors (ETDs) are based on ion mobility spectrometry (IMS) and can detect a wide range of explosive compounds at picogram to nanogram levels under optimal conditions. The amounts of three common explosives (RDX, PETN, and TNT) that trace detectors should be able, at a minimum, to detect were determined by testing in the Surface and Microanalysis Science Division (SMSD) of NIST. These amounts are not threat based (agency-specific and sensitive information), but instead are based on the capabilities of the technology. Minimum performance standards based on this information were promulgated through ASTM Committee E54 on Homeland Security Applications as ASTM E2520–07, "Standard Practice for Verifying Minimum Acceptable Performance of Trace Explosive Detectors."

A NIST Standard Reference Material (SRM) 2906 designed to support ASTM E2520-07 has been developed, and it contains three explosives solutions and one blank solution that can be used to prepare test samples. End users prepare samples on-site by depositing the SRM solutions onto the tickets or swipes used in ETDs, allowing them to dry and then using them immediately. SRMs have the highest level of confidence assigned to values such as concentration, and they are stable enough to be stored for extended times until they are purchased by customers. Trace deposits of explosives, however, are known to evaporate/sublime over time or be unstable on many surfaces. To remove the need for end-user preparation of samples, SMSD has adopted an alternative approach by distributing materials designated as test materials (TMs). The TMs are prepared and distributed for immediate use within a time frame over which we have confidence in the value assignments. Inkjet printing technology is used as the dispensing method to prepare TMs, and it offers a highly reproducible, automated method that allows for mass production of samples. The imprecision in inkjet production of TMs is typically less than 1 percent, while the uncertainty in the mass of trace explosive deposited on each TM is governed by the analytical uncertainty of the explosive stock assay, usually less than 4 percent as reported on the certificates. After inkjet production, the TMs are stable within these uncertainties for at least 30 days. TMs have been shipped to

federal partners to evaluate deployed ETDs and have proven useful in identifying instruments that are underperforming, even though they are in service. The general ease of use of the TMs allows for routine evaluation of ETDs, providing a tool to track the performance over time of deployed units. Tools that aid in better decision making about need for repair and return to service will save agency resources, particularly when applied to large inventories of ETDs.

A higher level performance standard is being developed in ASTM E54 (WK19817) to provide a realistic, well-defined, and defensible method for the determination of Limits of Detection (LODs) in field-deployed ETDs. The LOD value determined for a detector represents the smallest amount of a given explosive compound that will elicit, in at least 95 percent of replicated measurements, a real response for that compound. From these values, appropriate alarm thresholds may be determined and set. An interactive website has been established for users of the proposed standard for inputting measurements. The data are evaluated, the LOD is calculated, and a report is returned to the user. The LOD method is being evaluated for nonexplosives in an ASTM interlaboratory test designed and implemented by NIST SMSD using inkjet-printed TMs.

Another equally critical component, and one that must be tested and improved, is the ability to collect optimally the sample—the microscopic particles of explosive in complex residues—and deliver it to the detector.

Sampling Improvements and Training

Testing the performance and detection limits of the ETD is one component in ensuring that the screening process works effectively. Another equally critical component, and one that must be tested and improved, is the ability to collect optimally the sample—the microscopic particles of explosive in complex residues—and deliver it to the detector. This function is accomplished primarily by two mechanisms: (1) contact sampling using a swab or swipe to rub a surface, and (2) aerodynamic sampling to remove particles and sweep them to the detection region. (Another mechanism is direct sampling of vapors, but this is limited to a relatively few high-vapor-pressure explosives.) Contact sampling is currently the dominant sampling approach used for ETDs; however, it is dependent upon human operators and is limited in throughput capabilities. Aerodynamic sampling, particularly when applied to targeted areas of the body such as shoes, is a sampling mechanism of the future.

Factors that affect the efficiency of contact sampling include the characteristics of the material from which the swab is made and the force applied during sampling. Standardized methods to evaluate different swab materials, under development in ASTM E54 (WK37674), employ testing apparatus already in use for adhesion measurements to control the force and speed of sampling. Manufacturers of ETDs can make these fundamental measurements to test their choices for ETD swab material to aid in future developments. These measurements have already been used to identify a swab material in current usage that has a very low collection efficiency compared with other types of swabs. The material has beneficial attributes in terms of low instrument background, but the overall screening process is compromised by the poor collection efficiencies. The instrument manufacturer is aware of the problem and is working on next-generation materials.

Force is such a critical factor during contact sampling that the training received by screeners through the Transportation Security Administration (TSA) includes instructions to swipe with "firm" pressure. What is meant by "firm" pressure is difficult to communicate in training, and a method was needed to test for compliance. NIST SMSD has employed a new approach to training for force application, utilizing force sensitive resistor (FSR) arrays available as thin sheets that can be placed under surfaces. The FSRs image and record the forces applied during sampling and provide feedback in terms of actual values that can then be related to improvements in alarm rates during screening. Training protocols using FSRs are under development, and there are plans to implement them in TSA-based screener training.

Standard Explosive Particles

Another important factor in effective testing and improvement of sampling protocols is the development of standard test particles of explosives. Sampling strategies are highly dependent on the size, shape, and stickiness of particles, whether the sampling mechanism is based on contact or aerodynamic sampling. The ultimate goal is to generate standard particle deposits that match the properties of trace deposits, including fingerprint oils and other components that may be present, but where the mass, size, and shape of the explosive particles are well known and characterized. NIST SRMs 2905 and 2907 were developed to simulate the residues produced by handling military and other types of explosives. The SRMs were prepared by coating inert substrates with low concentrations (<0.5 percent) of Composition C-4, TNT, TATP, and Semtex. Because of the low concentrations of explosives in the simulant particles, large numbers of particles can be weighed to achieve the nanogram levels of explosives needed to test ETDs, simplifying the preparation of test samples.

Another approach to developing simulant particles is to formulate polymer-based spherical particles containing explosives. The explosive content can be as high as 70 percent in each particle, and the size can be directly controlled through processing parameters. An additional advantage is the ability to encapsulate volatile explosives and enhance their lifetimes. These particles are particularly useful for studies of aerodynamic sampling processes, because they can be produced in large numbers, and a spherical shape improves the ability to model particle release and transport.

A third approach is to use inkjet printing to deposit very small volumes of solution on nonwetting surfaces, where each small deposit would represent a single particle. Arrays of particles produced in this manner are transferred to test surfaces by physical contact, which is an effective process for a variety of surfaces. This type of "dry transfer" approach is already utilized by other federal agencies as a mechanism for testing ETDs, but without the control of the effective particle size achievable through inkjet printing. The advantage of this approach is that the particles are the actual explosive compounds, and other materials can be added to the arrays to mimic the plastic binders common to many explosive formulations and fingerprint oils.

Environmental Contamination

Finally, a critical component in realistic evaluation of ETD performance is the inclusion of environmental contaminants in the test materials. Sampling procedures will collect materials from the environment in addition to the explosive traces. Collection swabs typically become dirty during routine sampling, indicative of environmental contaminants. Aerodynamic sampling will sweep dirt and dust along with airborne particulate material into the collection zone. Chemical backgrounds or contamination may consist of soils, dust, pollen, particulate matter, soot, ashes, and whatever else has been tracked into an ETD deployment area. These contaminants may elicit a variety of effects, including false positive alarms, false negatives (masking effects), and system degradation.

To formulate a standard "dirt," NIST SMSD has developed an approach using a mixture of internationally available natural matrix SRMs. As certified SRMs, they are accepted as definitive materials that are homogeneous, sterilized, and stabilized and are characterized for a large number of chemical compounds. Four different SRMs have been used to formulate a mixture designated Simulated Interferent Material #1, or SIMdirt-1: a natural sediment, an agricultural soil, a mix of household dusts, and an urban air particulate. This fourth component, diesel particulate matter, is highly IMS active and contains substantial amounts of nitrate and volatile organic combustion products. This material represents air particles that, because of their small diameters (1 µm to less than 100 nm), have long lifetimes in the atmosphere and are ubiquitous pollutants, especially along transportation corridors and in urban and naval settings. A low level of air particulate would be expected to be present at many security checkpoints, so this component represents about 1 percent of the blend by mass. Together in SIMdirt-1, the four components represent four source types of environmental contamination anticipated at ETD deployment areas and originate from regions across the United States. Additional components can be included in SIMdirt-1 to simulate specific sampling environments where additional sources of environmental contamination are known to exist.

Conclusions

Significant progress has been made in developing a standards infrastructure around trace explosives detection. All these efforts—from the development of reference materials for testing deployed ETDs to the establishment of standard protocols for evaluating sampling procedures—lead to a higher level of confidence in the screening process. They also provide the framework for the development of next-generation technologies and procedures, which is necessary to match the evolving threat posed by terrorism.

¹W.A. MacCrehan, "A NIST Standard Reference Material (SRM) to Support the Detection of Trace Explosives," *Analytical Chemistry*, Vol. 81, No. 17 (2009), pp. 7189–7196; and W.A. MacCrehan, S. Moore, and D. Hancock, "Development of SRM 2907 Trace Terrorist Explosives Simulants for the Detection of Seintex and Triacetone Triperoxide," *Analytical Chemistry*, Vol. 83, No. 23 (2011), pp. 9054–9059.

²R.A. Fletcher et al., "Fabrication of Polymer Microsphere Particle Standards Containing Trace Explosives Using an Oil/Water Emulsion Solvent Extraction Piezoelectric Printing Process," *Talanta*, Vol. 76, No. 4 (2008), pp. 949–955.

About the Author

Jennifer Verkouteren, a research scientist at NIST, has worked in the areas of trace explosives and narcotics detection for 8 years. She has authored numerous peer-reviewed publications and has developed ASTM standards in these areas. She works with a group at NIST to support other federal partners, including TSA, the Department of Homeland Security, and the Department of State, in the deployment of trace contraband detection equipment.

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What Every First Response Organization Should Know About Its CBRN Respirators

By Richard Metzler and Jonathan Szalajda



The 2008 annual report of the InterAgency Board (IAB) for Equipment Standardization and Interoperability underscored the need, by the emergency responder community, for guidance and information on the selection, use, and maintenance of respiratory protective devices (RPDs) with chemical, biological, radiological, and nuclear (CBRN) protective capabilities. Specifically, the IAB stated that the CBRN RPDs were needed "to ultimately reduce incidences of respiratory related injury for nearly 4 million career and volunteer corrections, emergency medical services, fire fighting, and law enforcement responders." The Department of Homeland Security's (DHS's) Standards Executive and the National Personal Protective Technology Laboratory (NPPTL), a division of the National Institute for Occupational Safety and Health (NIOSH), teamed with the IAB to address that need.

Project Overview

The project to research, develop, test, and implement technical standards and authoritative information and guidance on CBRN RPDs required the collaboration of several federal agencies and other organizations. Federal agencies included, in addition to DHS, the Department of Commerce, Department of Defense, Department of Justice, National Institute of Standards and Technology, Occupational Safety and Health Administration (OSHA), and U.S. Army Research, Development and Engineering Command. Other organizations whose support was essential for the successful development and implementation of the NIOSH CBRN RPD standards included the following:

- International Association of Fire Chiefs
- International Association of Fire Fighters
- International Safety Equipment Association
- Memorial Institute for the Prevention of Terrorism
- National Fire Protection Association (NFPA).

These partnerships and collaborations have substantially advanced the RPD technical standards, the actual respirator equipment, and the applications designed to protect emergency responders against the threats posed by chemical warfare agents, biological hazards, radiological particulates, and toxic industrial chemicals.

CBRN respirators approved by NIOSH have unique performance and design characteristics that need to be considered when establishing an effective respiratory protection program. To properly protect responders using these specialized respirators, a respiratory protection program administrator must know the particular care, use, and maintenance requirements for these respirators.

Guidance information is being developed in several forms, including a comprehensive technical reference handbook, a training aid for self-contained breathing apparatus (SCBAs), and fact sheet primers focused on each CBRN respirator type approved by NIOSH. The fact sheets address SCBAs, air-purifying respirator (APR) gas masks, powered air-purifying respirators (PAPRs), and air-purifying escape respirators (APERs).

The fact sheets also explain how to read and understand NIOSH approval labels and provide guidance related to PAPR batteries. The CBRN respirator handbook and fact sheets have been drafted and are being peer reviewed. They are expected to be published later this year. Two fact sheets have been posted on the NPPTL website:

- "NIOSH Approval Labels—Key Information to Protect Yourself"
- "What's Special about CBRN Self-Contained Breathing Apparatus (SCBA)?"

CBRN Protection—Key Standards and Tests

To acquire a NIOSH certificate of approval for a respirator with CBRN protection, an applicant must first obtain a NIOSH approval for the respirator type meeting the requirements in Title 42, Part 18, of the Code of Federal Regulations. The applicant must also nieet additional national and international requirements—for example, NFPA, ASTM International, military, and European standards—and must pass special tests for CBRN protection specified by NIOSH.

Among the NIOSH-specified tests (with the CBRN RPD types to which they apply identified in parentheses) are the following:

- Chemical agent permeation and penetration resistance against distilled sulfur mustard (HD) and Sarin (GB), commonly referred to as a live-agent test (all CBRN RPD types)
- Laboratory respirator protection level (LRPL) (all CBRN RPD types)
- Canister gas/vapor challenge and breakthrough concentration service life tests and particulate filter efficiency tests (APR, PAPR, APER).

Below are examples of some key national and international requirements:

- Durability/environmental conditioning (APR, APER, PAPR with tight-fitting facepieces)
- Minimum packaging configurations (APR, APER, PAPR with tight-fitting facepieces)
- Breathing resistance (SCBA, APR, PAPR with tight-fitting facepieces, APER)
- Carbon dioxide and oxygen levels (SCBA, PAPR with loose fitting hoods, APER)
- Canister/cartridge color code (APR, PAPR)
- Mechanical connector, gasket, tolerance analysis (APR)

- Field of view, lens material haze, luminous transmittance, and lens abrasion resistance (APR)
- Communications (APR)
- Fogging (APR, APER)
- Flammability and heat resistance in accordance with NFPA Standard 1981 (SCBA, APER with carbon monoxide protection)
- Training and donning time (APER)
- Useful life (APER).

Examples of Special CBRN RPD Requirements

CBRN RPDs have unique selection, use, maintenance, and storage requirements that they must meet in order to pass the NIOSH-specific tests. This section addresses a few key requirements for illustrative purposes.

The test of chemical agent permeation and penetration resistance against distilled HD and GB defines the performance of various types of NIOSH-approved respirators with CBRN protection. On the basis of laboratory tests specifically defined for each respirator type, the following cautions and limitations are placed on the use of the NIOSH-approved CBRN RPDs:

- CBRN SCBAs should not be used beyond 6 hours after initial exposure to chemical warfare agents (liquid or vapor) to avoid the possibility of agent permeation.
- CBRN APR gas masks should not be used beyond 8 hours after initial exposure to chemical warfare agents to avoid the possibility of agent permeation or penetration. If liquid droplet exposure is encountered, the CBRN APR must not be used for more than 2 hours.
- CBRN PAPRs, whether tight fitting or loose fitting, must not be used beyond 8 hours after initial exposure to chemical warfare agents to avoid the possibility of agent permeation or penetration. If liquid droplet exposure is encountered, the CBRN PAPR with a tight-fitting facepiece and CBRN canister demonstrated the ability to be used for up to, but not more than, 2 hours. The CBRN PAPR with a loose-fitting hood and CBRN cartridge must not be used when liquid droplet exposure is encountered.

CBRN APRs are unique in several ways compared to industrial APRs. They are evaluated by NIOSH to ensure that each CBRN canister can provide the specified level of protection on all facepieces that are a component of a NIOSH-approved CBRN APR assembly, regardless of manufacturer. NIOSH ensures the interoperability of the components through design requirements controlling the respirator's facepiece and canister connector and the canister's physical characteristics. NIOSH also ensures that the use of facepieces and canisters from different manufacturers and NIOSH-approved CBRN

assemblies will not adversely affect the fit of the respirator facepiece. OSHA may permit the interoperable use of CBRN APR facepieces and canisters among NIOSH-approved CBRN APRs during emergencies only. However, when assembled with the facepiece from one manufacturer and the CBRN canister of another manufacturer, the respirator assembly is not NIOSH approved and may not provide the same performance features (e.g., breathing resistances) as an approved assembly. Thus, mixing CBRN facepieces and CBRN canisters among NIOSH-approved respirators during nonemergency operations is not permitted.

NIOSH subjects CBRN APRs and their required components to environmental and durability conditioning tests in the manufacturer-specified minimum packaging configuration (MPC). CBRN canisters are also subjected to additional rough-handling drop tests in their designated MPC. The MPC is the protective packaging in which the end user will store or maintain the CBRN APR and the required components. The end user is the person who will derive protection from the respirator by wearing it. Failure to store the CBRN APR in the manufacturer's recommended MPC may allow damage that could affect the APR or its components to provide the expected level of protection. The damage may not be detectible by the user prior to use. Examples of common MPCs are hard plastic carriers, clamshell containers, drawstring plastic bags, and hermetically sealed canister bags. Each manufacturer is likely to have unique packaging. The manufacturer's user instructions and the full NIOSH approval label will identify the required MPC.

NIOSH evaluates CBRN APR and PAPR canisters in laboratory tests for concentrations of gas or vapor breakthrough (passing through the canister) at various flow rates, concentrations, and durations. NIOSH tests and rates the canister to the minimum laboratory service life (test time) specified by the manufacturer. These tests evaluate whether gas or vapor will break through the CBRN APR and its canister under specific laboratory conditions. For less than a 60-minute service life, the canister capacity is specified in 15-minute intervals, identified by a capacity level. A designation of Cap1 refers to a laboratory-rated service life of 15 minutes, Cap2-30 minutes, and Cap3-45 minutes. The canister must meet or exceed the manufacturer's specified service life during the laboratory test without exceeding the NIOSH-identified breakthrough concentration level for the test gas or vapor. Workplace conditions are rarely identical to laboratory-controlled tests. Therefore, the actual in-use service life of a CBRN APR or PAPR may differ from the NIOSH laboratory-rated performance. A change schedule should be established by the person responsible for respirator use.

An LRPL test provides important information on the protection capability of each CBRN respirator, assesses the clarity of the manufacturer's user instructions, and uses feedback from human test subjects to appraise practical performance. The acceptable LRPL value and test conditions vary depending on the CBRN RPD type. The following represents LRPL test specifications for each CBRN RPD type:

- APER. The measured LRPL for each APER must be ≥2,000 for 95 percent of the trials, sampled in the breathing zone of the respirator, and it must be ≥150 for 95 percent of the trials sampled outside the breathing zone (under the hood). The respirator is tested in an atmosphere containing 20–40 mg/m³ corn oil aerosol of a mass median aerodynamic diameter of 0.4–0.6 µm.
- APR gas masks. The measured LRPL for each APR gas mask must be ≥2,000 when the APR facepiece is tested in an atmosphere containing 20–40 mg/m³ corn oil aerosol of a mass median aerodynamic diameter of 0.4–0.6 μm. Some tests are done to confirm that the facepiece can be used effectively with a canister of the maximum allowable weight of 500 grams and dimensions permitted by NIOSH requirements. This additional modified test for CBRN APRs evaluates the ability of the respirator facepiece to properly fit if used in an emergency interoperable configuration with a canister from another manufacturer's NIOSH-approved CBRN APRs.
- PAPR. The LRPL for each PAPR must be 10,000 for ≥95 percent of the trials with the blower operating in an atmosphere containing 20—40 mg/m³ corn oil aerosol of a mass median aerodynamic diameter of 0.4—0.6 μm. For tight-fitting PAPRs only, the LRPL must be 2,000 for ≥95 percent of the trials with the blower not operating. A modified LRPL using a sample size of eight subjects must be used for evaluation.
- SCBA. The measured LRPL for each open-circuit positive pressure SCBA must be ≥500 when the SCBA facepiece is tested without the benefit of the air cylinder and the positive pressure inside the mask (negative pressure mode) in an atmosphere containing 20–40 mg/m³ corn oil aerosol of a mass median aerodynamic diameter of 0.4–0.6 µm.

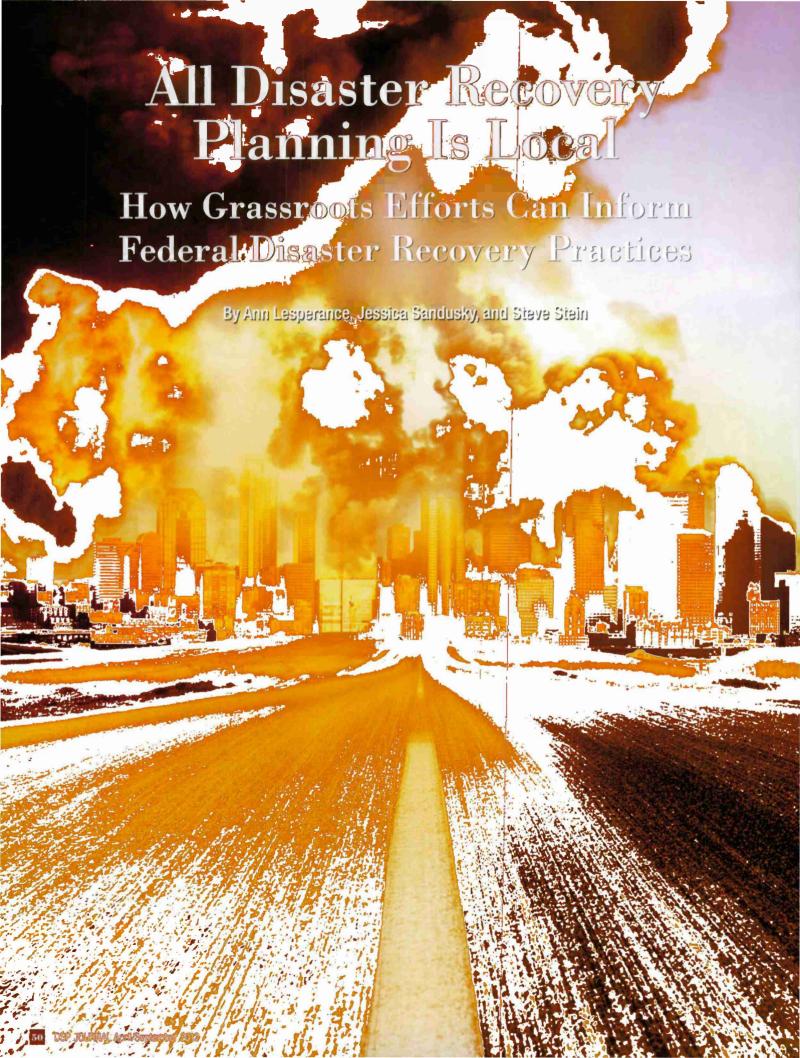
The above examples illustrate the types of key information provided in the guidance documents being developed. When the completed guidance documents are available, respiratory protection program administrators should obtain them and carefully follow the CBRN respirator manufacturer's instructions applicable to each CBRN RPD. This information can be integrated into CBRN respiratory protection programs and responder training.

For more information on the availability of these documents, contact Mr. Jonathan Szalajda at JSzalajda@cdc.gov.

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Richard Metzler, a respiratory protection consultant and past director of the NIOSH NPPTL, has more than 37 years of experience in occupational safety and health. He is a director of the International Society for Respiratory Protection, Americas Section; a member of the American National Standards Institute (ANSI) Z88 Respiratory Protection Committee; chair of the ANSI Z88.2 Practices for Respiratory Protection Committee; and a member of the American Industrial Hygiene Association's Respiratory Protection Committee.

Jonathan Szalajda is the chief of the Policy and Standards Development Branch at the NIOSH NPPTL. The branch develops and promulgates personal protective equipment (PPE)-related standards and regulations. Mr. Szalajda has worked in the field of respiratory protection and PPE for 25 years. He is currently the vice chair of ANSI Z88 Respiratory Protection Committee and is involved with several other ANSI and NFPA standards committees.



The National Disaster Recovery Framework provides a flexible set of guidelines for state and local communities to recover from accidental, natural, and intentional disasters. It focuses on how best to restore, redevelop, and revitalize the health, social, and economic aspects of a community. This framework takes a top-down approach but recognizes that one size does not necessary fit all. It has been said that all disasters are local; accordingly, all recovery processes and approaches should also be local. Yet the lessons learned from these grassroots efforts can also help federal agencies prepare for disasters as well. For example, much of the federal doctrine indicates that federal support is in assistance to the local jurisdictions, so grassroots efforts (or bottom-up approaches) should inform federal response and recovery.

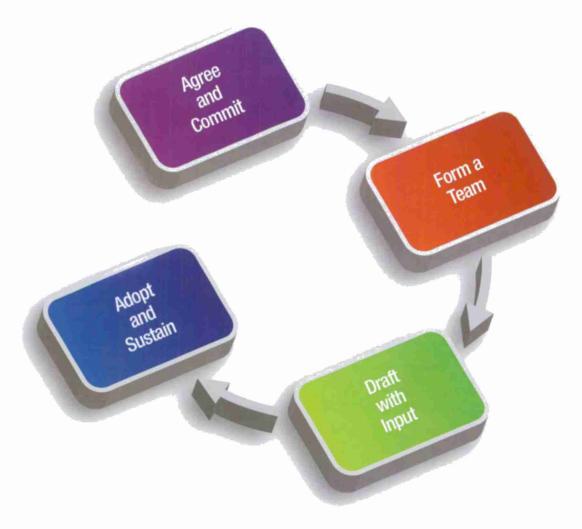
This article discusses a bottom-up approach to recovery planning, the elements of a local recovery framework, and the advantages and challenges of this approach. The presented approach has been used in two major urban areas. The results show that a grassroots approach to recovery planning can provide local jurisdictions with the context needed to develop achievable recovery plans, support critical recovery decisions at the state or regional level, and determine how federal agencies can most effectively engage in the multiagency decision-making process. The efforts were funded by the Department of Homeland Security's Science and Technology Directorate through a partnership with the Seattle, WA, and Denver, CO, urban areas and with local, state, and federal organizations, including the Department of Defense.

Grassroots Recovery Planning

Around the nation, a number of communities have been actively planning for recovery. For example, in 2010, stakeholders in the Seattle Urban Area Security Initiative (UASI), in partnership with the Defense Threat Reduction Agency and the Department of Homeland Security, developed a recovery framework focused on the aftermath of a biological attack. This disaster recovery framework lays out the policy considerations, the decisions that will need to be made, and the process for making those decisions in a disaster, with the goal of providing a standard for local jurisdictions to write their own operational recovery plans. The Seattle framework has since been used to develop recovery plans around the region. In 2011 and 2012, the Denver UASI, the state of Colorado, and partners developed an all-hazards recovery framework, which is being finalized. Both of these efforts led to a number of lessons learned that can inform recovery planning at the federal, state, and local levels.

The process to develop a recovery plan or framework is as important as the product itself. Grassroots disaster recovery should follow a four-step process, depicted in Figure 1. First, all agencies having jurisdiction in emergencies need to agree on the necessity of a recovery framework, and they need to commit to providing resources (for example, personnel, time, and attention) to its development. The agencies then need to form a team to guide development. This team must work with stakeholders and subject matter experts to draft a framework. Local emergency responders often work together to create response protocols, procedures, and agreements to ensure adequate response. What recent incidents and exercises have shown, however, is that recovery will take much longer, involve organizations outside of the typical emergency responder community, and be more complex than any other phase of emergency management. For this reason, recovery planning needs to cast a wide net to ensure involvement from relevant local agencies, state agencies, federal agencies with a local presence, the private sector (businesses and critical infrastructure owners), and other nongovernmental organizations such as Volunteer Organizations Active in Disasters and faith-based groups. Workshops can help introduce organizations to each other and assist them with identifying and working through potential issues as they provide input to the framework.

FIGURE 1. The Four-Step Process for Taking a Grassroots Approach to Disaster Recovery Planning



Once all stakeholders have had a chance for input and, where appropriate, have reviewed the draft, the agencies must take the final step and decide on how to adopt and sustain the framework. Who owns the framework? How will it be exercised to ensure it is improved? How will it be communicated to and shared with other agencies and stakeholders? How often will it be reviewed and updated, and who provides input? These questions should be addressed before the initial version of the framework is finalized.

Elements of a Recovery Framework

The specific sections to include in a recovery framework will vary according to the needs of the implementing organizations. Below are some general sections that may be useful:

- Background—summarizing the approach taken, the phases of recovery (short, intermediate, and long terms, according to the National Disaster Recovery Framework), the purpose of the framework, its intended use, and the organizations involved in its development and implementation.
- Assumptions—specifying existing decisions or conditions of the area covered by the framework and identifying roles and functions key to recovery. This includes assumptions having to do with what may have or should have occurred in the response phase.
- Multiagency Decision-Making Process—describing how agencies will work together for recovery. Having this decision-making process documented and agreed upon by all agencies is particularly important for expediting long-term recovery. This is especially critical when the event has impacts that include multiple municipalities or counties.
- Recovery Support Functions—describing recovery support functions, which are specific areas important to recovery, and laying out their scope, key considerations, and policy issues. These functions should align with those in the National Disaster Recovery Framework but be tailored to the challenges of the local area. Examples of challenges experienced by local jurisdictions are debris management, prioritization of cleanup, and volunteer and donation management.

Some local agencies have also developed a particular scenario to help the framework development team and stakeholders visualize and resolve issues. These scenarios can be patterned after the national planning scenarios.

Advantages to Grassroots Recovery Planning

Taking a grassroots approach to recovery planning has a number of advantages. Because a local recovery framework is developed for a specific location, the scope is usually more workable. In addition, developing the framework with stakeholder involvement ensures that key recovery support functions are identified and ready to be staffed. A local framework can serve as a key communication tool to inform state agencies about recovery plans and improve resiliency. It can also serve as a communication tool for federal agencies involved in supporting local planning. Finally, the framework allows local jurisdictions to identify appropriate threats and the approach for recovering from them within a local context. Current federal philosophies are focused on whole-of-community approaches to recovery and resilience, which emphasize the need for local engagement with the private sector, nongovernmental organizations, etc. The plans and approaches developed at the local level need to link to the federal government so it can provide the appropriate support and assistance to the local jurisdictions.

Challenges

Agencies following this grassroots model of recovery planning have encountered several challenges. One of the most difficult to resolve is the concept of multijurisdictional decision making. Many agencies realize that a catastrophic disaster will require multiagency coordination for recovery, but few have experience with such coordination. In a disaster, a wide variety of organizations seek to support response and recovery. How will decisions be made regarding what gets priority for cleanup and who will make them? How will other agencies be kept informed or involved? When multiple jurisdictions have specific responsibilities, how can they collaborate for better solutions? Developing a recovery framework allows these questions to be addressed in advance and increases the chances for a timely recovery.

Another key challenge is effectively involving the private sector. Again, many agencies agree that community recovery means economic recovery. Without the full support and engagement of private-sector businesses and critical infrastructure owners, such recovery is impossible. Agencies need to meet with representatives from the private sector in workshops or at trade events to learn what businesses need from government to prepare and to recover. What are businesses prepared to do for themselves? What can't they do? For example, workshops in the Seattle area during framework development identified a 6-month window for recovery, after which some companies would simply move out of the area or go out of business.

A third challenge concerns the specialized expertise needed to develop realistic recovery plans for chemical, biological, and radiological incidents. Although such incidents are often of most concern to major urban areas, any community near a chemical or nuclear plant also faces the potential for accidental releases of hazardous materials. Local agencies may need help from state and federal agencies, as well as from the private sector, to understand and plan for recovery from such incidents. The Denver UASI and state of Colorado regional recovery framework includes annexes describing recovery support functions for chemical, biological, and radiological incidents. These annexes were developed with input from subject matter experts from the Environmental Protection Agency, Centers for Disease Control and Prevention, and Department of Energy.

Finally, local and state agencies seem to struggle to understand the role of the federal government in disaster recovery. Fears abound of federal takeovers of local jurisdictions, either from the military or some other agency. Local areas need to work with their state and federal counterparts to identify federal roles for supporting local jurisdictions during emergency response and recovery. Possible areas of support include financial (grants, subsidies, loans), equipment, technical expertise, and staffing. How federal agencies will engage in the multiagency coordination process is also a key issue to resolve. Knowing, before a disaster, what local agencies may need can help federal agencies tailor their support, saving time and money.

Importance of Local Recovery Planning

Developing a local or regional disaster recovery framework will help reduce the time and resources required to restore communities and critical infrastructure following a catastrophic incident and will assist policymakers and emergency managers with minimizing the economic and public health impacts. As was the case with the efforts in Seattle and Denver, lessons learned at the local level can inform practices at the federal level and result in communities that are better prepared and more resilient.

For more information, visit the Pacific Northwest National Laboratory's Northwest Regional Technology Center for Homeland Security (NWRTC) website: http://nwrtc. pnnl.gov.

About the Authors

For more than 30 years, Steve Stein, director of the Pacific Northwest National Laboratory's NWRTC, has worked with government agencies, private-sector entities, and other nongovernmental organizations on evaluation, development, testing, and insertion of new technologies. He specializes in leading large, complex, multidisciplinary projects.

Ann Lesperance, NWRTC's deputy director for regional programs, works with organizations to accelerate the demonstration and deployment of new homeland security technologies and approaches. Her experience spans 25 years in environmental and public health analysis, project management, and program development.

Jessica Sandusky is a research scientist at Pacific Northwest National Laboratory. She has experience providing technical support and conducting research and analysis on issues relating to national security, various regional economies, environmental and emergency management conditions, and policies. **

Program Livews

Topical Information on Standardization Programs







DSPO Hosts International Standardization Workshop

DSPO hosted its International Standardization Workshop on May 15–17, 2012. The workshop, held at LMI in McLean, VA, brought attendees from the United States, Canada, France, and Germany to participate in discussions pertaining to all aspects of international standardization. This event gave attendees the opportunity to exchange ideas and best practices, learn about new initiatives, and network with familiar and new acquaintances.

Mr. Stephen Lowell, DSPO's deputy director, kicked off the event with introductions and a briefing on the U.S. Defense Standardization Program, including its origins, its policies and procedures, and the types of standards under its purview. Other presentations included the following:

- "NATO Standardization and Enhancing the Customer Focus," presented by Mr. Roger Golden, Office of the Under Secretary of Defense (Acquisition, Technology and Logistics, International Cooperation Office) and U.S. representative to the NATO Committee for Standardization
- "United States' Policy and Guidance on International Standardization," presented by Ms. Latasha Beckman, DSPO's program manager for international standardization

- "An Overview of Standardization within NATO and Its Importance in Terms of Achieving Interoperability," presented by Lt Col Joseph Hall, NATO Standardization Agency
- "The Global Role of the Materiel Standardization Harmonization Team," presented by Colonel (Armament) Jean Luc Le Doré, Defence Standardization Center, France, highlighting the importance of using civilian standards for international standardization applications.

In addition, presentations were given by representatives from the international standardization program offices of the U.S. military departments, such as Dr. B. Jon Klauenberg, Department of the Air Force, Human Effectiveness Directorate, on "Managing Standards in Multinational Environments" and Mr. Richard Kurasiewicz, Department of the Army, on the "Multinational Program (NATO and ABCA) Update."

Workshop attendees also were given demonstrations of the NATO Terminology Management System, the NATO Standardization Document Database, and the ASSIST Online Database.

This 3-day workshop was a success. It provided attendees with opportunities to ask questions during presentations and, during a roundtable discussion on the last day, to engage with presenters in dialogue on standardization challenges and successes.

For more information about DSPO workshops and training opportunities, please visit our website at www.dsp.dla.mil. To get copies of the 2012 International Standardization Workshop presentations, please call 703-767-6872.

OMB Requests Information on Addressing Standards and Conformity Assessment Issues

The Office of Management and Budget (OMB) recently announced a request for information (RFI) to allow interested stakeholders the opportunity to provide input to OMB, the National Institute of Standards and Technology, federal regulators, and other relevant agencies on how the federal government should address emerging issues in standards and conformity assessment. OMB requested feedback on the following specific issues:

 Agency implementation of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities." In rulemaking, are federal agencies generally following the guidance in the circular?



- Standardization activities. OMB Circular A-119 does not establish a preference between consensus and nonconsensus standards. What factors should agencies use in evaluating which standards to use in regulation, procurement, or other nonregulatory activities? What are the respective roles of consensus versus nonconsensus standards?
- Conformity assessment. Should an OMB Circular A-119 supplement be issued to establish relevant principles on conformity assessment? If so, what should be addressed in the supplement?
- Protection of copyright associated with standards. Standards are considered intellectual property and are typically copyrighted by the standards developing body. Some parties have raised transparency concerns with the availability of these standards when they are referenced or incorporated in regulation, and compliance with these documents is mandatory. What concerns or best practices have arisen in relation to copyright and incorporation by reference in regulation?
- Consensus standard and cost-benefit analysis. Federal agencies need to have a basic understanding of the costs associated with the development of private-sector standards in comparison to the overall costs for developing government-unique standards. These data points are invaluable to determining when it is practical or impractical to incorporate a consensus standard into regulation. How do the costs for developing a consensus standard compare to developing a government-unique standard?
- Using and updating standards in regulation. Federal agencies have various methods of using standards as a basis for regulation and updating standards that are referenced or incorporated into regulation. Should OMB establish best practices on how to reference/incorporate standards in regulation? Should OMB supplement Circular A-119 to establish best practices for updating standards referenced in the regulation as standards are revised?
- Use of more than one standard or conformity assessment procedure in a regulation or procurement solicitation. At times, a regulation or procurement solicitation may have a requirement that can be met by more than one standard and more than one conformity assessment procedure. Should OMB provide guidance to agencies on when it is appropriate to allow the use of more than one standard or conformity assessment procedure to demonstrate conformity with regulatory requirements or solicitation provisions?

OMB is reviewing the RFI responses to determine next steps.

Events Upcoming Events and Information

October 11, 2012, Washington, DC World Standards Day

The U.S. celebration of World Standards Day will take place on October 11, 2012, at the Fairmont Hotel in Washington, DC. This year's theme is "Standards Increase Efficiency." For more information about the 2012 World Standards Day celebration, exhibition, reception, and dinner, please go to http://www.ansi.org/meetings_events/ WSW12/wsd.aspx?menuid=8.

October 30-November 1, 2012, Salt Lake City, UT

PSMC Fall 2012 Meeting

The Parts Standardization and Management Committee (PSMC), chartered by DSPO, will hold its fall meeting in Salt Lake City, UT. The meeting will be hosted by L-3 Communications at the Holiday Inn and Suites Salt Lake City Airport West. The agenda will include presentations on current parts management topics and breakout sessions for subcommittees to work specific tasks. If you are involved in parts management and are interested in participating, please contact Donna.McMurry@dla.mil or call 703-767-6874. Additional meeting information will be posted on the PSMC website: http://www.dscc.dla.mil/Programs/ Psmc/.

People

People in the Standardization Community

Farewell

In April 2012, **Richard Yannitti** retired from the Commodities Engineering Flight for the Air Force Global Logistics Support Center at Wright-Patterson Air Force Base, OH, after more than 38 years of dedicated military and civilian service. During the many years he worked in support of the DSP, he played a key role in the DoD Parts Management Program reengineering effort. He represented the Air Force on the Parts Standardization and Management Committee (PSMC). He served on the ad hoc committee that studied the DoD Parts Management Program and made recommendations to improve it. In recent years, he served as the military co-lead of the PSMC, one of its top three leaders. In addition to sharing his technical expertise and leadership skills, his optimism and can-do approach helped improve the cohesiveness of the parts management community.

Beverly Wilson of the Defense Logistics Agency (DLA) Land and Maritime, Columbus, OH, retired on June 1, 2012, with over 41 years of federal service. During the last 27 of those years, she worked in support of the DSP. She played a key role in the DoD Lead Standardization Activity function. In addition to representing DLA Land and Maritime on several committees, she played a major part in developing and defining new standardization opportunities. For that, she received the 2010 Defense Standardization Program Award for "Weapons Systems Provisioning Data and Standardization Complement Each Other." Ms. Wilson's dedication and positive approach contributed significantly to the support of the warfighter through standardization.

Thomas Ridgway of DSPO has retired after 43 years of loyal federal service. He led several engineering and standardization initiatives for DLA and the Office of the Secretary of Defense and also served as the DLA Standards Improvement Executive. Mr. Ridgway became DLA's first technical and quality process owner and later served as the deputy executive director for Materiel Process Management. Most recently, he has served as DSPO's program manager for the DoD Joint Standardization Boards and also developed a standardization template for use by the DoD standardization community.

Upcoming Issues Call for Contributors

We are always seeking articles that relate to our themes or other standardization topics. We invite anyone involved in standardization—government employees, military personnel, industry leaders, members of academia, and others—to submit proposed articles for use in the *DSP Journal*. Please let us know if you would like to contribute.

Following are our themes for upcoming issues:

Issue	Theme
October/December 2012	Non-Government Standards
January/March 2013	Biometrics Standardization

If you have ideas for articles or want more information, contact Nicole Daddario, Editor, *DSP Journal*, Defense Standardization Program Office, 8725 John J. Kingman Road, STOP 5100, Fort Belvoir, VA 22060-6220 or e-mail DSP-Editor@dla.mil.

Our office reserves the right to modify or reject any submission as deemed appropriate. We will be glad to send out our editorial guidelines and work with any author to get his or her material shaped into an article.



